

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF TEXAS  
MARSHALL DIVISION**

ROCHESTER DRUG CO-OPERATIVE,  
INC., on behalf of itself and all others  
similarly situated,

*Plaintiff,*

v.

ALLERGAN, INC.,

*Defendant.*

Civil Action No. 2:17-cv-766

**JURY TRIAL DEMANDED**

**CLASS ACTION COMPLAINT & JURY TRIAL DEMAND**

## TABLE OF CONTENTS

I.	INTRODUCTION .....	1
II.	PARTIES .....	4
III.	JURISDICTION AND VENUE .....	5
IV.	CLASS ALLEGATIONS .....	6
V.	REGULATORY BACKGROUND .....	9
A.	The Benefits of Generic Drug Competition to the Class .....	11
1.	Prices drop upon entry of the first AB-rated generic.....	12
2.	Prices plummet when additional AB-rated generics enter the market. ....	12
B.	Patent Protection for Branded Drugs .....	13
1.	Patent portfolios protect blockbuster drugs from competition. ....	13
2.	Because patent prosecutions are non-adversarial, patent applicants are subject to special oaths and duties designed to protect the public interest in the PTO’s issuance of valid and lawfully obtained patents. ....	14
C.	NDAs and Patent Listings in the FDA’s Orange Book .....	15
D.	ANDAs, Orange Book-Related Generic Manufacturer Certifications, and Related Litigation.....	16
1.	Hatch-Waxman provides for an automatic 30-month stay of FDA ANDA approvals upon filing of a patent suit. ....	17
2.	Hatch-Waxman incentivizes generics to challenge questionable patents before launch by awarding 180-day exclusivity to the first paragraph iv-certified ANDA filer.....	18
E.	The Citizen Petition Process .....	19
F.	Proceedings Before the PTAB .....	22
VI.	FACTUAL ALLEGATIONS .....	24
A.	FDA Approval of Restasis .....	24

B.	Allergan Prosecutes Serial Patent Applications to Extend Restasis Monopoly .....	27
1.	The PTO repeatedly rejects Allergan’s serial efforts to obtain additional patents for “new” combinations of castor oil and cyclosporine that were obvious in light of prior art. ....	27
2.	In 2009, Allergan concedes that all its “new” cyclosporine/castor oil combination claims are obvious in light of Ding I. ....	28
3.	Facing the imminent May 2014 expiration of Ding I, in August 2013, Allergan files a series of continuation applications, all deriving from the ’177 application. ....	29
4.	Allergan’s alleged new 2013 data and unexpected results were neither new nor unexpected, and they fraudulently induced the PTO to grant the Second Life Patents. ....	31
C.	Allergan Wrongfully Lists Invalid Second Life Patents in the Orange Book.....	33
D.	One or More ANDA Applicants Would Have Been Ready, Willing, and Able to Manufacture and Distribute Commercial Quantities of Generic Restasis in May 2014 Upon Expiration of Ding I.....	34
E.	Allergan Files Sham Patent Infringement Suits to Delay Generic Entry.....	36
F.	Allergan Abuses Citizen Petition Process to Delay Generic Entry .....	38
G.	Allergan Enters Sham Agreement with the Tribe.....	44
VII.	MARKET POWER AND DEFINITION .....	47
VIII.	MARKET EFFECTS AND CLASS DAMAGES .....	51
IX.	ANTITRUST IMPACT AND INTERSTATE COMMERCE .....	53
X.	CLAIMS FOR RELIEF .....	54
XI.	PRAYER FOR RELIEF .....	64
XII.	JURY DEMAND .....	65

Plaintiff, ROCHESTER DRUG CO-OPERATIVE, INC. (“Plaintiff”), on behalf of itself and all others similarly situated, files this civil antitrust action against Defendant ALLERGAN, INC. (“Allergan” or “Defendant”), for Allergan’s unlawful monopolization of the market for prescription Restasis (cyclosporine ophthalmic emulsion) sales in the United States. Based upon personal knowledge, information, belief, and investigation of counsel, Plaintiff specifically alleges:

## **I. INTRODUCTION**

1. This case arises from Allergan’s unlawful scheme to extend its monopoly in the market for cyclosporine emulsion eyedrops, sold in the United States under the brand name Restasis, as a prescription treatment for dry-eye disease (“DED”). Restasis is a blockbuster drug: in 2016, Allergan’s total Restasis sales in the United States alone were approximately \$1.4 billion.

2. As is typical of branded pharmaceutical products, Restasis has enjoyed a patent-protected monopoly, originating from U.S. Patent No. 5,474,979 (the “’979 Patent” or “Ding I patent”) and certain related patents that were issued in or before 1995 and expired no later than May 17, 2014.

3. In 2013, Allergan hatched a scheme to extend its patent monopoly and thereby prevent competition from the cheaper generic substitutes that were prepared to enter once the patent protection was gone. This multifaceted monopolistic scheme included the following anticompetitive conduct:

4. *First*, in 2013, Allergan fraudulently induced the United States Patent and Trademark Office (“PTO”) to issue a second set of patents covering Restasis (referred to herein as the “Second Life Patents”). In fact, Allergan had been trying for years to convince the PTO to issue these continuation patents and had met with repeated rejection on the grounds that the purported inventions were “obvious” in light of the earlier Restasis patents. To overcome those

objections, Restasis submitted fraudulent and misleading declarations from two of its in-house scientists that convinced the PTO examiner to grant the Second Life Patents. These Second Life Patents were obvious and should not and would not have been granted but-for Allergan's fraudulent conduct during the prosecution.

5. *Second*, Allergan wrongfully listed the Second Life Patents in the Food and Drug Administration's ("FDA") Orange Book. By doing so, any potential generic competitor either would be required to wait to launch until after the expiration of the Second Life Patents, or would be required to provide notice of the intention to launch before the expiration of the Second Life Patents. Providing this notice triggers the patent holder's right to sue for infringement, and the mere initiation of such a lawsuit within 45 days automatically triggers a 30-month stay of the FDA's approval of the potential generic competitor's Abbreviated New Drug Application ("ANDA"). Thus, by listing its fraudulently obtained Second Life Patents, Allergan was able to game the regulatory system to prevent approval of competing generic versions of Restasis.

6. *Third*, Allergan filed sham patent litigation against the ANDA filers who sought to market generic versions of Restasis. Allergan knew that the Second Life Patents were invalid in light of prior art, and thus knew that those patents were unenforceable. But as Allergan knew when it filed the sham lawsuits, the mere filing of the lawsuits triggered the automatic 30-month stay of the FDA's approval of the ANDAs, thus providing Allergan with an unlawful extension of its monopoly.

7. *Fourth*, shortly after wrongfully listing its invalid patents in the Orange Book, Allergan began filing repetitive sham citizen petitions with the FDA, urging the FDA not to approve the filed ANDAs absent certain scientific studies. Allergan filed multiple petitions on the

same subject, despite the FDA's rejection of the arguments, with the purpose and effect of delaying the FDA's approval of the would-be generic competitors.

8. *Fifth*, Allergan entered into a sham license agreement with the Saint Regis Mohawk Tribe (the "Tribe"), whereby Allergan transferred the patents to the Tribe and then licensed the patents back. According to this Court, "[u]nder the terms of the agreements between Allergan and the Tribe, the Tribe will receive \$13.5 million upon execution of the agreement and will be eligible to receive \$15 million in annual royalties." *Allergan, Inc. v. Teva Pharm. USA, Inc.*, No. 2:15-cv-1455, 2017 WL 4619790, at \*1 (E.D. Tex. Oct. 16, 2017). Further, this Court summarized the substance of this deal as follows: "The essence of the matter is this: Allergan purports to have sold the patents to the Tribe, but in reality it has paid the Tribe to allow Allergan to purchase—or perhaps more precisely, to rent—the Tribe's sovereign immunity in order to defeat the pending [inter partes review] proceedings in the PTO." *Id.* at \*2. This sham transaction was entered into to wrongfully forestall generic competition.

9. Allergan's intent in engaging in this long-running, multifaceted scheme was to use governmental processes to foreclose generic competition and thereby maintain its Restasis monopoly. The effect of the scheme was to net Allergan billions of dollars in revenue at the expense of direct purchasers, such as Plaintiff and all others similarly situated. Consequently, Plaintiff and the proposed class have been deprived of the opportunity to purchase generic versions of Restasis and have paid hundreds of millions of dollars in overcharges. This suit seeks to hold Allergan accountable for its manipulation of the PTO, the FDA, and the federal judiciary in violation of the antitrust laws, and the resultant damages to Plaintiff and other Class members.

## II. PARTIES

10. Plaintiff Rochester Drug Co-Operative, Inc. is a stock corporation duly formed and existing under the New York Cooperative Corporations Law, with a principal place of business located at 50 Jet View Drive, Rochester, New York 14624. Plaintiff purchased Restasis directly from Defendant during the class period. Defendant's anticompetitive conduct directly injured Plaintiff, as described in greater detail below.

11. Defendant Allergan, Inc. is a corporation organized under Delaware state law with its principal place of business located in Irvine, California. Allergan is the holder of approved New Drug Application ("NDA") No. 50-790 for Cyclosporine Ophthalmic Emulsion, 0.05%, sold under the Restasis trademark. Allergan also was the applicant for and holder of each of the six Second Life Patents Allergan has claimed cover Restasis: U.S. Patent No. 8,629,111 (dated Jan. 14, 2014); U.S. Patent No. 8,633,162 (dated Jan. 21, 2014); U.S. Patent No. 8,642,556 (dated Feb. 4, 2014); U.S. Patent No. 8,648,048 (dated Feb. 11, 2014); U.S. Patent No. 8,685,930 (dated Apr. 1, 2014); and U.S. Patent No. 9,248,191 (dated Feb. 2, 2016). As of September 8, 2017, Allergan purports to have transferred its ownership interests in the Second Life Patents to the Saint Regis Mohawk Tribe.

12. The actions described in this complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Allergan's officers, agents, employees, or other representatives while actively engaged in the management of Defendant's affairs within the course and scope of their duties and employment, and/or with Defendant's actual, apparent, and/or ostensible authority.

### III. JURISDICTION AND VENUE

13. This action arises under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, and Section 4 of the Clayton Act, 15 U.S.C. § 15(a), and seeks to recover threefold damages, interest, costs of suit, and reasonable attorneys' fees for the injuries sustained by Plaintiff and other Class members resulting from Defendant's unlawful anticompetitive foreclosure of cyclosporine sales in the United States. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a), and 15 U.S.C. § 15.

14. Venue is proper in this district pursuant to 15 U.S.C. §§ 15(a), 22, and 28 U.S.C. §§ 1391(b), (c), and (d) because during the Class Period (defined below), Allergan resided, transacted business, was found, or had agents in this district, and a substantial portion of the alleged activity affected interstate trade and commerce discussed below has been carried out in this district. Significantly, during the Class Period, Allergan has maintained and continues to maintain significant offices and operations in Texas. During the Class Period, Allergan operated a facility in Texas where it manufactured and distributed numerous pharmaceutical products, including Restasis, whose nationwide distribution is coordinated from a site in Texas. In addition, venue is proper in this district because Allergan has availed itself of this judicial district by purposefully selecting this venue to pursue the sham patent infringement lawsuits against generic competitors, which litigation was part of the multifaceted anticompetitive scheme alleged in this Complaint. *See Complaint, Allergan, Inc. v. Teva Pharm. USA, Inc.*, No. 2:15-CV-1455-WCB, ECF 1 (E.D. Tex. Aug. 24, 2015).

15. Defendant's conduct, as described in this complaint, was within the flow of, was intended to have a substantial effect on, and did have a substantial effect on, the interstate commerce of the United States, including in this district.

16. During the Class Period, Defendant manufactured, sold, and shipped Restasis in a continuous and uninterrupted flow of interstate commerce, which included sales of Restasis in this district, advertisement of Restasis in media in this district, monitoring prescriptions of Restasis by prescribers within this district, and employment of product detailers in this district, who as agents of Defendant marketed Restasis to prescribers in this district. Defendant's conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce, including commerce within this district.

17. This Court has personal jurisdiction over Defendant. Defendant, throughout the United States and including in this district, has transacted business, maintained substantial contacts, or committed overt acts in furtherance of the illegal scheme. The scheme has been directed at, and has had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this district.

#### **IV. CLASS ALLEGATIONS**

18. Plaintiff, on behalf of itself and all other similarly situated direct purchasers, seeks damages, measured as overcharges, trebled, against Defendant based on allegations of anticompetitive conduct in the market for Restasis and its AB-rated generic equivalents.

19. Plaintiff brings this action on behalf of itself and, under Federal Rules of Civil Procedure 23(a) and (b)(3), as a representative of a Class of direct purchasers (the "Class" or "Direct Purchaser Class") defined as follows:

All persons who or entities which purchased Restasis in the United States or its territories and possessions, including the Commonwealth of Puerto Rico, directly from Allergan at any time after May 17, 2014, through and until the anticompetitive effects of Defendant's conduct cease (the "Class Period").

Excluded from the Direct Purchaser Class are Defendant and its officers, directors, management, employees, subsidiaries, or affiliates, and all federal governmental entities.

20. Members of the Direct Purchaser Class are so numerous that joinder is impracticable. Plaintiff believes that the Class is composed of scores of entities. Further, the Direct Purchaser Class is readily identifiable from information and records in Defendant's possession.

21. Plaintiff's claims are typical of the Direct Purchaser Class claims. Plaintiff and all Class Members were damaged by the same wrongful conduct of the Defendant, i.e., they paid artificially inflated prices for cyclosporine ophthalmic emulsion and were deprived of earlier and more robust competition from less-expensive generic cyclosporine ophthalmic emulsion as a result of Allergan's wrongful conduct.

22. Plaintiff will fairly and adequately protect and represent the interests of the Direct Purchaser Class. The interests of the Plaintiff are coincident with, and not antagonistic to, those of the Direct Purchaser Class.

23. Plaintiff is represented by counsel with experience in the prosecution of class-action antitrust litigation, and with particular experience with class-action antitrust litigation involving pharmaceutical products.

24. Questions of law and fact common to the members of the Direct Purchaser Class predominate over questions that may affect only individual Class Members because Defendant has acted on grounds generally applicable to the entire Direct Purchaser Class, thereby making overcharge damages with respect to the Direct Purchaser Class as a whole appropriate. Such generally applicable conduct is inherent in Allergan's wrongful conduct.

25. Questions of law and fact common to the Direct Purchaser Class include:

- i. whether Allergan willfully obtained and/or maintained monopoly power over Restasis and its generic equivalents;
- ii. whether Allergan fraudulently obtained the Second Life Patents;

- iii. whether Allergan unlawfully excluded competitors from the market for Restasis and its AB-rated generic equivalents;
- iv. whether Allergan filed sham lawsuits to enforce the Second Life Patents;
- v. whether Allergan unlawfully delayed or prevented generic manufacturers of cyclosporine ophthalmic emulsion from entering the market in the United States;
- vi. whether Allergan's agreement with the Tribe was an illegal agreement in restraint of trade;
- vii. whether Allergan maintained monopoly power;
- viii. whether the law requires definition of a relevant market when direct proof of monopoly power is available, and if so the definition of the relevant market;
- ix. whether Allergan's activities as alleged herein have substantially affected interstate commerce;
- x. whether, and if so to what extent, Allergan's conduct caused antitrust injury (i.e., overcharges) to Plaintiff and Class Members; and
- xi. the quantum of aggregate overcharge damages to the Class.

26. Class-action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

27. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

## **V. REGULATORY BACKGROUND**

28. Branded drug companies can obtain valid patents that cover new prescription drug products. These patents, intended as an incentive and reward for pursuing true invention, provide the patentee with the right to seek to exclude infringing competitors for a length of time set under a statute by Congress. Thus, branded drug companies have a statutory period of time to charge very high prices for medications that, in fact, cost little to manufacture. But it is a limited period, after which would-be competitors may enter the market with lower-cost substitutes.

29. Once the lawful periods of patent exclusivity expire on brand products, would-be competitors can seek FDA approval to sell generic versions of the brand, allowing those companies to manufacture generic products that are just as safe and effective as, but far less expensive than, the brand. The medication becomes affordable for all, and purchasers are no longer burdened by the high cost of the brand drug.

30. The timing of approval of these competing products, however, can depend on, among other things, the truthfulness of the patent information provided by the brand to the FDA. In particular, a branded drug company is required to provide the FDA information about any patents covering a particular drug product, and the FDA publicizes this information so that would-be generic competitors understand the scope of the brand's ostensible patent protection. But the FDA must rely completely on the brand manufacturer's truthfulness about patent validity and applicability because the FDA does not have the resources or authority to verify the manufacturer's patents.

31. A potential generic competitor must wait to launch until the expiration of all listed patents, unless it can certify that its generic product does not infringe one or more listed patents (or that such patents are invalid or not enforceable). Such a certification, however, permits the brand company to sue for patent infringement (if it has a Rule 11 basis to do so) to prevent the

generic competitor from launching. But a brand company may only file an infringement suit if it has an objectively reasonable basis to claim the patent's protection. The listed patents, would-be competitors' certifications, and the brand company's infringement suits all affect the timing of FDA approval of generic equivalents.

32. As a further guard against error in the patent prosecution process that may result in improvidently issued patents, Congress recently established an "inter partes review" ("IPR") process that empowers the Patent Trial and Appellate Board ("PTAB") to review the validity of a previously issued patent, and, if the PTAB determines that the challenger "has a reasonable likelihood of prevailing on at least one of the challenged claims," it will conduct a trial on the invalidation issues in which the patent holder is the defendant.

33. From this framework, some basic rules emerge. First, brand drug companies seeking patent protection, like all patentees, owe a duty of candor and forthrightness in dealing with the PTO, *see* 37 C.F.R. § 1.56, which can be breached by, among other things, submitting false information to the PTO with the intent to deceive. Second, brand drug companies cannot provide false or misleading patent or other drug information to the FDA and wield that information to delay entry of less expensive generic medications containing the same molecule as the brand product beyond the expiration of legitimate patent protection. Third, drug companies cannot file patent infringement lawsuits against would-be competitors when the action has no realistic likelihood of success of the merits; the mere filing of such a lawsuit stalls legitimate efforts to gain market entry. Fourth, federal policy favors prompt invalidation of improvidently issued patents; patent holders cannot knowingly wield invalid patents as anticompetitive weapons and evade the consequences.

34. Allergan broke all of these basic rules.

**A. The Benefits of Generic Drug Competition to the Class**

35. Generic versions of brand name drugs contain the same active ingredient and are determined by the FDA to be just as safe and effective as their brand name counterparts. The only material difference between generic drugs and their corresponding brand name versions is their price. Because generic versions of a corresponding brand drug product are commodities that cannot be differentiated, the primary basis for generic competition is price. Typically, generics are at least 10% less expensive than their brand name counterparts when there is a single generic competitor, and this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market for a given brand. Consequently, the launch of a generic drug usually results in significant cost savings to all drug purchasers.

36. Since the passage of the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (“FDCA”), every state has adopted substitution laws that either require or permit pharmacies to substitute AB-rated generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise). Substitution laws and other institutional features of pharmaceutical distribution and use create the economic dynamic wherein the launch of AB-rated generics results both in rapid price decline and rapid sales shift from brand to generic purchasing. Once a generic equivalent hits the market, the generic quickly captures sales of the corresponding brand drug, often capturing 80% or more of the market within the first six months. This results in a loss of revenue for the brand drug manufacturer, but dramatic savings for the American public. In a recent study, the Federal Trade Commission (“FTC”) found that on average, within a year of generic entry, generics had captured 90% of corresponding brand drug sales and (with multiple generics on the market) prices had dropped 85%. As a result, competition from generic drugs is viewed by brand name drug companies, such as Allergan, as a grave threat to their bottom lines.

37. Generic competition enables all members of the proposed Class to: (a) purchase generic versions of the drug at substantially lower prices; and/or (b) purchase the brand drug at a reduced price.

38. Until a generic version of the brand drug enters the market, however, there is no bioequivalent generic drug to substitute for and compete with the brand drug, and therefore the brand manufacturer can continue to profitably charge supracompetitive prices. Brand manufacturers, such as Allergan, are well aware of generics' rapid erosion of their brand sales. Brand manufacturers thus seek to extend their monopoly for as long as possible, sometimes resorting to any means possible—including illegal means.

**1. Prices drop upon entry of the first AB-rated generic.**

39. Experience and economic research show that the first generic manufacturer to enter the market prices its product below the price of its branded counterpart. Every state either requires or permits a prescription written for the brand drug to be filled with an AB-rated generic. Thus, the first generic manufacturer almost always captures a large share of sales from the branded form of the molecule. At the same time, there is a reduction in average price paid for a prescription for the molecule.

**2. Prices plummet when additional AB-rated generics enter the market.**

40. When multiple generic competitors enter the market, competition accelerates and prices drop to their lowest levels. Multiple generic sellers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing costs.

41. According to the FDA and the FTC, the greatest price reductions occur when the number of generic competitors goes from one to two. In that situation, there are two commodities that compete on price. Some typical estimates are that a single generic launch results in a near-

term retail price reduction of at least 10%, but that with two generic entrants, near-term retail price reduction is about 50%.

42. Soon after generic competition enters the market, the vast majority of the sales formerly enjoyed by the brand shift to the generic sellers. In the end, total payments to the brand manufacturer of the drug decline to a small fraction of the amounts paid prior to generic entry. Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price. According to the Congressional Budget Office, generic drugs save consumers an estimated \$8 billion to \$10 billion a year at retail pharmacies. Billions more are saved when hospitals use generics.

## **B. Patent Protection for Branded Drugs**

### **1. Patent portfolios protect blockbuster drugs from competition.**

43. There is a predictable pattern to the way brand drug companies develop their patent portfolios for blockbuster drugs. The first group of patents in the brand drug company's portfolio for the drug may reflect a genuine technological breakthrough that may later contribute to the success of the drug; these initial patents usually cover the active compound in a prescription drug or a particular pharmaceutical composition and may be correspondingly robust.

44. After filing applications for the original patents, the company continues its research and development efforts in the hopes of developing a drug product that could, eventually, be approved by the FDA. As the company's research matures, the patent filings continue, often for narrow modifications relating to specific formulations, methods of using the drug, or processes for creating the drug product disclosed in the original patent filings. But the original patent filings are now in the "prior art" and thus limit the scope of follow-on patents that can be obtained. New patents can be obtained for features of the drug only if the brand drug company can show that the new features are non-obvious distinctions over the growing body of prior art, which includes

patents and printed publications, among other things. And often methods of using earlier inventions are disclosed by earlier compound or composition patents. Over time, as the number of patent filings for the drug grows, so does the volume of prior art beyond which the brand drug company must show non-obvious distinctions.

45. Patents present, at minimum, obstacles for would-be generic competitors to design around. Some patents broadly cover a drug's active ingredient and—if valid and enforceable—may prove impossible to design around while meeting the FDA's criteria for equivalent generics. While generic versions of the brand product may be able to obtain FDA approval and enter the market before all patents expire, once all the valid patents covering its blockbuster drug have expired, the brand drug company has no lawful means of trying to prevent competitors from entering the market.

46. Therefore, a typical patent portfolio for a brand drug has its most significant patents issuing first; over time, the later-issued patents generally become increasingly narrow and more difficult to obtain. Even if the narrower coverage is obtained, these later-issuing patents are more vulnerable to attack as invalid for covering subject matter that is old or obvious, and the narrower coverage is more easily designed around by would-be generics, thus preventing the brand from satisfying its burden of proving infringement to keep generics out of the market.

**2. Because patent prosecutions are non-adversarial, patent applicants are subject to special oaths and duties designed to protect the public interest in the PTO's issuance of valid and lawfully obtained patents.**

47. Because patents often enable a branded-product manufacturer to exclude competition and charge supracompetitive prices, it is crucial as a policy matter that any patent underlying a branded drug be valid and lawfully obtained.

48. Patent prosecutions are non-adversarial. Thus, in order to help assure that the “public interest is best served” though the PTO's issuance of patents that are valid and lawfully

obtained, patent applications are subject to various special oaths and duties. Among these various special oaths and duties is the Duty of Disclosure, Candor, and Good Faith, which requires the applicant to disclose to the PTO “all information known . . . to be material to patentability,” including with respect to prior art. *See* 37 C.F.R. § 1.56. And this duty extends not only to each and every named inventor on the patent application but to each and every “attorney or agent who prepares or prosecutes the application” as well as “[e]very other person who is substantively involved in the preparation or prosecution of the application.” *Id.* § 1.56(c). Where fraud on the PTO “was practiced or attempted” or the Duty of Disclosure, Candor, and Good Faith “was violated through bad faith or intentional misconduct” no patent should be granted. *Id.* § 1.56(a).

### **C. NDAs and Patent Listings in the FDA’s Orange Book**

49. Under the FDCA, drug companies that wish to sell a new drug product must file an NDA with the FDA. An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.

50. To notify other drug manufacturers, a manufacturer of a new drug product must tell the FDA about patents that it believes cover its drug products. The FDA then publishes a list of those patents in the publicly available publication commonly called the “Orange Book.” Patents issued after NDA approval may be listed in the Orange Book within 30 days of issuance. Once patents are listed in the Orange Book, potential generic competitors are on notice regarding the patents that are claimed to relate to the brand name drug.

51. The brand name drug manufacturer can list its patents in the Orange Book by filing a Form 3542 with the FDA. Under the FDA rules, the branded manufacturer is only permitted to list patents that are reasonably enforceable. Form 3542 expressly asks the applicant whether the drug presents a “No Relevant Patent” situation (i.e., a situation where there are no patents that could be reasonably asserted in an infringement lawsuit). Form 3542 likewise requires the

signatory to affirm, under penalty of perjury, that all the patent information submitted to the FDA on each patent that claims the drug substance, drug product, or method of use that is the subject of the approved NDA or supplement is complete and accurate.

52. The FDA performs only a ministerial act in listing the patents identified by the brand manufacturer in the Orange Book. The FDA does not have the resources or authority to verify the manufacturer's representations for accuracy or trustworthiness and relies completely on the manufacturer's truthfulness about the validity and applicability of any Orange Book-listed patents.

**D. ANDAs, Orange Book-Related Generic Manufacturer Certifications, and Related Litigation**

53. In 1984, Congress passed the Hatch-Waxman Amendments to the FDCA. The Hatch-Waxman Amendments were designed to speed the introduction of low-cost generic drugs to market by permitting a generic manufacturer to file an ANDA with the FDA that may rely on the scientific findings of safety and effectiveness included in the brand name drug manufacturer's original NDA, requiring only a showing that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand name drug. The premise—codified by Congress and implemented by the FDA for the past 30 years—is that two drug products that contain the same active pharmaceutical ingredient, in the same dose, delivered in the same way, and absorbed into the blood stream at a similar rate over a similar period of time are expected to be equally safe and effective.

54. At the same time, the Hatch-Waxman Amendments also sought to protect pharmaceutical companies' incentives to create new and innovative products, by, among other things, permitting a brand company to file a legitimate patent infringement lawsuit against a generic before the generic brings its product to market.

55. The Hatch-Waxman Amendments achieved both goals, substantially advancing the rate of generic product launches, and ushering in an era of historically high profit margins for brand name pharmaceutical companies.

**1. Hatch-Waxman provides for an automatic 30-month stay of FDA ANDA approvals upon filing of a patent suit.**

56. The Hatch-Waxman Amendments created a procedural mechanism to provide some time for brand and generic manufacturers to resolve patent litigation before generic products launched, while also providing that, after that period, a generic is free to decide to launch “at risk” before the patent suit is resolved.

57. Once one or more patents are listed in the Orange Book, a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any of those patents to obtain FDA approval of that ANDA. A generic manufacturer can make one of four certifications:

- i. that no patent for the brand name drug has been filed with the FDA;
- ii. that the patent for the brand name drug has expired;
- iii. that the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date; or
- iv. that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer’s proposed product.

58. If an ANDA filer provides a so-called paragraph iv certification, a brand manufacturer can sue the ANDA filer for patent infringement (assuming it has a Rule 11 basis to do so). If the brand name manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notification of the paragraph iv certification, the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the entry of a final judgment on a decision by a court that the patent is invalid or not infringed by the generic manufacturer’s ANDA. Until one of those conditions occurs, the FDA cannot authorize the generic

manufacturer to go to market with its product. The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

59. The brand manufacturer could file patent infringement claims more than 45 days after receiving the paragraph iv certification but doing so would not trigger the automatic 30-month stay of FDA approval.

**2. Hatch-Waxman incentivizes generics to challenge questionable patents before launch by awarding 180-day exclusivity to the first paragraph iv-certified ANDA filer.**

60. Pursuant to the Hatch-Waxman Amendments, the first generic manufacturer to file an ANDA containing a paragraph iv certification receives 180 days of market exclusivity. This means that other, secondary ANDA-filers will not be able to launch their own generic products for at least six months after the first generic—known as the “first-filer”—launches its product.

61. During this 180-day exclusivity period, the first-filer is the only ANDA-approved generic manufacturer on the market. As recognized by the Supreme Court, this 180-day exclusivity period is very valuable, and it is often the case that most of a first-filer’s profits are earned during this 180-day exclusivity period. *FTC v. Actavis*, 570 U.S. 136, 133 S. Ct. 2223, 2229 (2013).

62. If the only versions of a drug on the market are the brand and the first-filer’s product, then the first-filer prices its product below the brand product, but not as low as if it were facing competition from other generics. Since in these circumstances the first-filer’s product may compete only with the brand, and because the branded company rarely drops the brand price to match the first-filer, the first-filer does not face the kind of price competition that arises when additional generic competitors enter the market.

**E. The Citizen Petition Process**

63. Pharmaceutical companies have multiple avenues and opportunities through which to communicate views to the FDA. For example, FDA holds public advisory meetings, which can be requested by pharmaceutical companies, to address issues regarding specific drug products or more generalized issues that pertain to many products. Additionally, there are industry and FDA forums for discussion that permit interaction and debate on pharmaceutical issues.

64. Among the available options, brand and other manufacturers and members of the public at large may file a petition with the FDA requesting, among other things, that the FDA take, or refrain from taking, any form of administrative action. This mechanism is commonly referred to as a “citizen petition”. Citizen petitions are intended to convey, for the FDA’s consideration, genuine concerns about safety, scientific, or legal issues regarding an FDA-regulated product and may be submitted any time before or after market entry.

65. A citizen petition may be filed to request that the FDA take action regarding drug-approval requirements, including those involving generic drugs. To move the FDA to grant this type of request, the petition must include supportive, clinically meaningful data, and the requested relief must be consistent with the FDA’s authority and with the Hatch-Waxman statutory and regulatory framework.

66. FDA regulations concerning citizen petitions require the FDA Commissioner to respond to each citizen petition within 180 days after the date on which the petition was submitted. That response may be to approve the request in whole or in part, or to deny the request. The Commissioner may also provide a tentative response with a full response to follow.

67. Reviewing and responding to citizen petitions is a resource-intensive and time-consuming task because, no matter how baseless a petition may be, the FDA must research the petition’s subject, examine scientific, medical, legal, and sometimes economic issues, and

coordinate internal agency review and clearance of the petition response. A response to a citizen petition and the approval of generic drugs are each considered final FDA actions that can be appealed under the Administrative Procedures Act. Meaning, a petitioner who does not agree with the FDA's response to a petition can sue the FDA (and many have), and seek to have the FDA's response overruled by a court. The FDA therefore needs to have a complete administrative record reflecting that its response was based on sound science, in part, to defend itself in any subsequent appeal. The FDA also must base its decisions about the fundamental safety and efficacy of drug products on sound science in order to protect those who take the drug products falling under its jurisdiction.

68. These activities strain the FDA's limited resources, and citizen petition reviews can delay FDA approval of generic products even if those petitions ultimately are found to lack any reasonable evidentiary, regulatory, statutory, or scientific basis.

69. Abusive and anticompetitive citizen petitions have become an increasingly common problem in the last several years, as brand-name companies have sought to compensate for dwindling new product pipelines. In some such cases, citizen petitions have been filed with respect to ANDAs that have been pending for more than a year, long after the brand-name manufacturer received notice of the ANDA filing, and have had the (intended) effect of delaying the approval of generic drugs while the FDA evaluates the citizen petition. One recent empirical study found that "[m]any citizen petitions from competitor companies appear to be last-ditch efforts to hold off generic competition. In fact, the most common grouping of petitions was those filed within six months of generic approval." Robin Feldman et al., *Empirical Evidence of Drug Pricing Games—A Citizen's Pathway Gone Astray*, 20 STAN. TECH. L. REV. 39, 70 (2017). Another found that between 2011 and 2015, the FDA denied 92% of section 505(q) citizen

petitions, the type most often employed to oppose generic entry—and the type Allergan filed here. See Michael A. Carrier & Carl Minniti, *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 AM. U. L. REV. 305, 332-33 & Tbl. 4 (2016).

70. FDA officials have further acknowledged abuses of the citizen petition process. Former FDA Chief Counsel Sheldon Bradshaw noted that in his time at the agency he had “seen several examples of citizen petitions that appear designed not to raise timely concerns with respect to the legality or scientific soundness of approving a drug application but rather to try to delay the approval simply by compelling the agency to take the time to consider arguments raised in the petition whatever their merits and regardless of whether or not the petitioner could have made those very arguments months and months before.”

71. It is well known in the pharmaceutical industry that it is FDA practice to withhold ANDA approvals until after its consideration of, and response to, a citizen petition is complete. On this subject, Director Buehler acknowledged that “[i]t is very rare that petitions present new issues that CDER has not fully considered, but the Agency must nevertheless assure itself of that fact by reviewing the citizen petitions.”

72. Delaying generic competition is a lucrative strategy for a brand-name manufacturer. Given the marketplace’s preference for generic over brand-name products, the cost of filing a citizen petition may be trivial compared to the value of securing even a few months of generic entry delay.

73. The abuse of the citizen petition process in part helped lead Congress to enact the FDA Amendments Act of 2007, 21 U.S.C. § 355(q) (the “FDAAA”), which added new section 505(q) to the FDCA providing that the FDA shall not delay approval of a pending ANDA because of a citizen petition unless the FDA determines that a delay is “necessary to protect the public

health.” The FDAAA, however, did not provide the FDA with additional resources to enable it to more promptly respond to petitions, but instead provides only that the FDA communicate its delay within 30 days of its determination that an ANDA approval delay was necessary. Thus, a brand manufacturer may still be able to delay generic approval while the FDA considers whether the relevant citizen petition implicates issues of public health, regardless of whether the petition actually does or not, and regardless of whether the petition has any merit. In the high-stakes world of pharmaceuticals, even relatively short delays can cost drug purchasers millions of dollars in overcharges.

74. Even after several years of experience under the FDAAA, the FDA continues to express concerns that citizen petitions are being filed for the purpose of delaying ANDA approvals: “FDA will continue to gain additional experience and monitor trend data in the FY 2012 reporting period to assist Congress in determining whether section 505(q) is accomplishing the stated goals of the legislation. Based on the petitions that FDA has seen to date, however, the agency is concerned that section 505(q) may not be discouraging the submission of petitions that do not raise valid scientific issues and are intended primarily to delay the approval of competitive drug products.” Dep’t of Health and Human Servs., FDA, *Report to Congress, Fourth Annual Report on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action for Fiscal Year 2011*.

#### **F. Proceedings Before the PTAB**

75. In 2011, Congress passed the Leahy-Smith America Invents Act (“Invents Act”) to address a widely held concern that invalid patents were being issued and enforced, to the detriment of both innovation and the economy. A centerpiece of the Act was the creation of new IPR proceedings, by which members of the public could challenge improperly issued patents and have them eliminated more quickly and inexpensively than through expensive and time-consuming

patent litigation. IPR proceedings also bore the promise of a review by technically-educated members of the PTAB who are familiar with the sciences at issue in any particular proceeding.

76. The Invent's Act allows the PTAB to review existing patents and extinguish those rights in an adversarial trial process. An IPR commences when a party—often an alleged patent infringer—petitions the PTAB to reconsider the PTO's issuance of an existing patent and invalidate it on the ground that it was obvious or anticipated by prior art.

77. The PTAB will grant a request for an IPR only if the challenger of the patent shows “a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). If it institutes an IPR, the review is conducted before a panel of three technically-trained administrative patent judges of the PTAB.

78. The PTAB must decide the review within one year of the institution date—significantly faster than invalidity issues would generally be adjudicated in a trial before a district court. Notably, the IPR review process can and frequently does take place simultaneously with parallel district court infringement litigation. The IPR process thus provides a speedy and economical mechanism for an accused patent infringer to challenge a wrongfully-issued patent.

79. The PTAB trial proceedings have become an exceedingly effective method of challenging improperly-granted patents—at least 84% of patents reaching a final written decision in PTAB validity challenges are adjudicated to have at least one invalid claim, and 69% have had all claims cancelled as invalid.<sup>1</sup> Given the high likelihood of claim cancellation once an IPR has been instituted, IPR proceedings have been called “patent death squads,” and patent holders are accordingly loathe to be subject to the IPR process.

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<sup>1</sup> Steve Brachmann & Gene Quinn, *Are more than 90 percent of patents challenged at the PTAB defective?*, IPWatchdog (June 14, 2017), available at <http://www.ipwatchdog.com/2017/06/14/90-percent-patentschallenged-ptab-defective/id=84343/> (last visited Dec. 8, 2017).

## VI. FACTUAL ALLEGATIONS

### A. FDA Approval of Restasis

80. Cyclosporine treats DED, also known as keratoconjunctivitis sicca (“KCS”), which “occurs when the quantity and/or quality of tears fails to keep the surface of the eye adequately lubricated.”<sup>2</sup> Symptoms can range from irritation to great discomfort to impaired vision.

81. Since 2003, Allergan has been selling the prescription drug cyclosporine under the brand name Restasis, an emulsion consisting of various components, including the active ingredient cyclosporin A,<sup>3</sup> an immunosuppressant, which is dissolved in castor oil, a fatty acid glyceride.

82. In 1993, Allergan licensed from Sandoz, Inc., the technology of treating aqueous-deficient dry eye with cyclosporine. That technology was the subject of U.S. Patent No. 4,839,342 (“the ’342 patent”), which claimed methods for enhancing or restoring lacrimal gland tearing comprising topically administering cyclosporine to the eye in a pharmaceutically acceptable vehicle, such as topical administration. The ’342 patent also recited the use of castor oil, among other compounds, as a pharmaceutically acceptable vehicle for delivering cyclosporine to the eye.

83. Because cyclosporine is highly insoluble in water, Allergan had to develop an oil-in-water emulsion castor oil (a hydrophobic vehicle that would dissolve the cyclosporine), together with an emulsifier and an emulsion stabilizer in water. Allergan disclosed and claimed this work in two patents, the first of which, titled “Nonirritating Emulsions For Sensitive Tissue”, issued in 1995 as U.S. Patent No. 5,474,979 (“the ’979 patent” or “the Ding I patent”). The Ding I patent

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<sup>2</sup> National Eye Institute of the National Institutes of Health, *Facts About Dry Eye*, available at <https://nei.nih.gov/health/dryeye/dryeye> (last visited Dec. 8, 2017).

<sup>3</sup> Cyclosporin A is sometimes spelled “cyclosporine” to distinguish it from other cyclosporins, such as cyclosporins B, C, and D. *See* U.S. Pat. No. 4,839,342, col. 3, ll. 7–11.

contained four examples, the first two of which contained multiple formulations drawn from the disclosed and claimed ranges of components. This range included 0.05% to 0.40% cyclosporine and 0.625% to 5.00% castor oil. The Ding I patent stated that the preferred weight ratio of cyclosporine to castor oil was below 0.16 (which is the maximum solubility level of cyclosporine in castor oil), and that the more preferred weight ratio of cyclosporine to castor oil was between 0.02 and 0.12.

84. The second patent, U.S. Patent No. 5,981,607 (“the ‘607 patent” or “the Ding II patent”), is titled “Emulsion Eye Drop for Alleviation of Dry Eye Related Symptoms in Dry Eye Patients and/or Contact Lens Wearers”. The Ding II patent disclosed and claimed a method for alleviating dry-eye-related symptoms by topically applying to ocular tissue an emulsion of a higher fatty acid glyceride, polysorbate 80, and an emulsion-stabilizing amount of Pemulen in water, all without cyclosporine.

85. In the late 1990s, Allergan began clinical trials of various combinations of cyclosporine and castor oil. In the first clinical trial (the “Phase 2” study), Allergan tested many of the combinations listed in Ding I, attempting to ascertain the appropriately safe and effective dosage (e.g., 0.1% cyclosporine with 1.25% castor oil; 0.2% cyclosporine with 2.5% castor oil). The results were published in the May 2000 journal of the American Academy of Ophthalmology, by Dara Stevenson et al., in the article *Efficacy and Safety of Cyclosporin A Ophthalmic Emulsion in the Treatment of Moderate-to-severe Dry Eye Disease, A Dose-Ranging, Randomized Trial*, 107 Ophthalmology 967 (May 2000). The study disclosed cyclosporine concentration in each formulation but not the castor oil concentration, and it concluded that all tested concentrations significantly improved the ocular signs and symptoms of moderate-to-severe dry-eye disease, and mitigated dry-eye disease’s effects on vision-related functioning. All tested concentrations were

safe and effective in increasing tearing in certain patient groups, and all outperformed the castor-oil-only group, though Stevenson did note that the castor-oil-only vehicle “performed well on its own, producing significant improvements from the baseline.” *Id.* at 973.

86. Notably, the Stevenson study concluded that there was no clear dose-response relationship between the 0.05% cyclosporine formulation and the formulations containing greater amounts of cyclosporine—efficacy did not increase with increases in dosage amounts. However, the 0.1% cyclosporine formulation “produced the most consistent improvement in objective and subjective endpoints (such as superficial punctate keratitis and rose bengal staining),” while the 0.05% cyclosporine formulation “produced the most consistent improvements in patient symptoms (such as sandy/gritty feeling and ocular dryness).” *Id.* at 974. Therefore, Stevenson’s study suggested that “subsequent clinical studies should focus on the cyclosporine 0.05% and 0.1% formulations.” *Id.*

87. The Phase 3 trials focused on the .05% and 0.1% formulations, as well as a castor-oil-only vehicle, with the results published in Kenneth Sall et al., *Two Multicenter, Randomized Studies of the Efficacy and Safety of Cyclosporine Ophthalmic Emulsion in Moderate to Severe Dry Eye Disease*, 107 *Ophthalmology* 631 (April 2000). Phase 3 confirmed the results of Phase 2, and found the 0.05% cyclosporine resulted in significantly greater improvements than castor oil alone, though castor oil alone also produced significant improvements over a patient’s baseline, suggesting that it was a contributing factor to the formulations’ success. Statistically, there was no significant difference between the 0.05% cyclosporine formulation and the 0.1% formulation in either Phase 2 or 3.

88. Following the Phase 3 study, Allergan filed an NDA with the FDA seeking authorization to market the 0.05% cyclosporine product that was tested in the Phase 3 trials. The

proposed commercial product, which is Restasis, would contain all of the components of the Phase 3 0.05% cyclosporine formulation, including 1.25% castor oil. The FDA approved the application in December 2002, authorizing the sale of Restasis for the following indication: “Restasis is a topical immunomodulator indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.”

89. Since its launch in 2003 up through the present, Restasis has been a true blockbuster product, generating billions of dollars of revenue.

**B. Allergan Prosecutes Serial Patent Applications to Extend Restasis Monopoly**

**1. The PTO repeatedly rejects Allergan’s serial efforts to obtain additional patents for “new” combinations of castor oil and cyclosporine that were obvious in light of prior art.**

90. For over a decade following the FDA’s approval of Allergan’s Restasis NDA, Allergan filed a variety of patent applications focusing on patenting various combinations of castor oil and cyclosporine, notwithstanding the earlier published work that already claimed a broad range of combinations with no statistically different outcomes based on the particular combination. Among others, Allergan filed U.S. Patent Application No. 10/927,857 (“the ’857 application”) on August 27, 2004. The ’857 application and dependent claims were again based on combinations of cyclosporine and castor oil within the range covered by Ding I. Allergan withdrew a number of the claims of the ’857 application, and, unsurprisingly, the PTO examiner rejected the remaining claims based in part on obviousness in light of the Ding I patent. The examiner concluded that it would have been obvious to modify the composition of Ding I by increasing the amount of castor oil from the amount found in Example 1D of the Ding I patent in order to reduce the ratio of the

cyclosporine component to the hydrophobic component from 0.08, since Ding I claimed ratios as low as 0.02 and amounts of castor oil ranging from 0.625% to 5%.

91. Allergan then amended the '857 application in 2007 to include a claim to an emulsion comprising water, 1.25% castor oil, and 0.05% cyclosporine, which is the percentage of those components in Restasis, and, as would be expected, the PTO examiner again rejected the application. Allergan appealed, and in 2007, while the appeal was pending, Allergan filed a continuation of the '857 application, U.S. Patent Application No. 11/897,177 ("the '177 application"). The '177 application was similar to the '857 application, but it added claims regarding new conditions that the method was asserted to treat, including corneal graft rejection.

**2. In 2009, Allergan concedes that all its "new" cyclosporine/castor oil combination claims are obvious in light of Ding I.**

92. In June 2009, Allergan made a filing in the prosecution of the applications that contradicted its earlier patentability claims, conceding that with respect to both the '857 and '177 applications, the various composition claims were obvious in light of Ding I:

The applicants concede that it would have been obvious to modify examples 1A-1E of the Ding reference to arrive at Composition II of the present application. The differences are insignificant. One need only use the cyclosporin concentration of Example 1E (0.05%), the castor oil concentration of Example 1D (1.250%), and the remaining ingredients of those examples. As the examiner correctly observes, one of ordinary skill in the art "would readily envisage" such a composition, especially in view of Example 1B: having selected 0.05% as the concentration of cyclosporin, Example 1B (wherein the ratio of cyclosporin to castor oil is 0.04) teaches that the concentration of castor oil should be 1.25% ( $0.05\% / 1.25\% = 0.04$ ). The applicants concede that in making this selection (0.05% cyclosporin and 1.25% castor oil) there would have been a reasonable expectation of success; the differences between Examples 1A-1E and Composition II are too small to believe otherwise.

The formulation of Composition II is squarely within the teaching of the Ding reference, and the Office should disregard any

statements by the applicants suggesting otherwise, whether in this application or in co-pending application no. 11/897,177.

93. Allergan withdrew its then-pending appeal of the examiner's rejection, canceled all of the previous claims, and added a new claim with a composition including an amount of cyclosporine of less than .05%. The examiner again rejected the new composition claim as obvious in light of Ding I (and for non-statutory double patenting over Ding I). By April 2011, a notice of abandonment was entered on the '857 application. The '177 application ultimately issued as U.S. Patent No. 8,618,064, but was narrowly limited to only the additional use for the treatment of corneal graft rejection.

**3. Facing the imminent May 2014 expiration of Ding I, in August 2013, Allergan files a series of continuation applications, all deriving from the '177 application.**

94. Having repeatedly failed to convince the PTO to grant patent protection over various "new" composition claims, and with the May 2014 expiration of Ding I on the immediate horizon, in August 2013, Allergan filed six additional continuation applications deriving, directly or indirectly, from the '177 application. These six additional applications were identical with only minor variations, modifying the prior specifications by adding four sentences that further described the role of cyclosporine as an immunosuppressant and the conditions that can be treated with cyclosporine. As this Court found when invalidating the patents that subsequently issued from these applications, "[t]he new applications were intended to protect the Restasis composition and the method of using that composition in treating dry eye and KCS after the expiration of the Ding I patent in 2014." *Allergan, Inc. v. Teva Pharms. USA, Inc.*, No. 2:15-CV-1455-WCB, 2017 WL 4803941, at \*10 (E.D. Tex. Oct. 16, 2017).

95. In initiating these 2013 applications, Allergan tried to claw back its prior concession that various cyclosporine-castor oil combinations were obvious in light of Ding I, claiming to have

new data supporting patentability, based on “unexpected results” showing the claimed Restasis formulation to be particularly effective, as well as “commercial success” and “long-felt need.” The PTO again rejected the claims presented by the 2013 applications as obvious in light of Ding I.

96. Responding to that rejection, Allergan submitted declarations executed in October 2013 from two of its scientists—Dr. Rhett Schiffman and Dr. Mayssa Attar—in an effort to show that the claimed formulation had produced new and unexpected results relative to the formulations set forth in Ding I and other prior art. Specifically, Allergan represented to the PTO examiner that new evidence demonstrated surprising test results in two objective testing parameters for dry eye—Schirmer tear testing and decreases in corneal staining—and two subjective testing factors—blurred vision and the use of artificial tears. For example, Allergan represented to the PTO that Dr. Schiffman’s declaration showed that:

surprisingly, the claimed formulation [of 0.05% cyclosporin and 1.25% castor oil] demonstrated an 8-fold increase in relative efficacy for the Schirmer Tear Test score in the first study of Allergan’s Phase 3 trials compared to the relative efficacy for the 0.05% by weight cyclosporin A/0.625% by weight castor oil formulation discussed in Example 1E of Ding, tested in Phase 2 trials. The data presented herewith represents the subpopulation of Phase 2 patients with the same reductions in tear production (x 5mm/5 min) as those enrolled in the Phase 3 studies. . . . Exhibits E and F also illustrate that the claimed formulations also demonstrated a 4-fold improvement in the relative efficacy for the Schirmer Tear Test score for the second study of Phase 3 and a 4-fold increase in relative efficacy for decrease in corneal staining score in both of the Phase 3 studies compared to the 0.05% by weight cyclosporin A/0.625% by weight castor oil formulation tested in Phase 2 and disclosed in Ding (Ding 1E). This was clearly a very surprising and unexpected result.

*Allergan*, 2017 WL 4803941, at \*11 (emphasis in original).

97. Based on Allergan’s representation of Dr. Schiffman’s discovery and the declaration itself, as well as a substantially similar declaration from Dr. Attar, the PTO examiner

reversed course and allowed the patents to issue with respect to all six applications, which issued in early 2014 as U.S. Patent Nos. 8,629,111 (“the ’111 patent”), 8,633,162 (“the ’162 patent”), 8,642,556 (“the ’556 patent”), 8,648,048 (“the ’048 patent”), 8,685,930 (“the ’930 patent”), and in 2016 as U.S. Patent No. 9,248,191 (“the ’191 patent”). These are the Second Life Patents at issue here.

**4. Allergan’s alleged new 2013 data and unexpected results were neither new nor unexpected, and they fraudulently induced the PTO to grant the Second Life Patents.**

98. In reality, the statements and data reflected in Allergan’s submissions to the PTO and the supporting declarations, which Allergan represented as presenting new and unexpected results, were not new. Instead, Dr. Schiffman’s declaration consisted of statements plagiarized from the article by Sall et al., which had relied on and first published Allergan’s own Phase 3 clinical trial data thirteen years earlier.

99. But not only was the “new” 2013 data not actually new, it did not actually demonstrate unexpected results. As this Court recently found, Allergan’s presentation to the PTO, which was “more advocacy than science,”

substantially overstated the difference between the clinical results obtained with the Ding formulations and the clinical results obtained with the Restasis formulation. The actual clinical results, interpreted properly, show no significant difference in efficacy between the Restasis formulation and the 0.1% formulation that was Example 1D of the Ding I patent.

*Allergan*, 2017 WL 4803941, at \*64.

100. In submitting the 2013 continuing applications, Allergan sought new patent protection on substantially the same claims that the PTO examiners had rejected on numerous prior occasions. These “new” claims were also negated by Allergan’s concession in 2009 of obviousness in light of prior art. The PTO examiners granted these claims only upon reliance on Allergan’s

Schiffman Declaration and Allergan's characterizations of "new" data and "surprising" results not contemplated by the prior art. Indeed, according to this Court, Dr. Schiffman "agreed that it would be fair to say that his declaration was instrumental in persuading the Patent Office to grant the applications." *Allergan*, 2017 WL 4803941, at \*20. But for this fraudulent declaration, the PTO would not have granted the Second Life Patents.

101. Allergan made these representations and characterizations, both by commission and omission, with the intent to deceive the PTO, and such representations and characterizations were material and fraudulently induced the PTO to grant the Second Life Patents. As this Court found:

To the extent that Allergan relies on Dr. Schiffman's presentation to the PTO, and the fact that the examiner concluded that unexpected results had been shown, the Court finds that the presentation made to the examiner in 2013, including Dr. Schiffman's declaration and the accompanying exhibits, *painted a false picture* of the comparative results of the Phase 2 and Phase 3 trials. In addition, that presentation *created the misleading perception* that the evidence that Dr. Schiffman relied on to show unexpected results was not known at the time of the invention. Accordingly, the Court regards the examiner's finding of unexpected results to be entitled to no weight, based as it was on evidence that *did not accurately depict* the comparative results of the two Allergan studies and that was, in any event, disclosed in the prior art.

*Allergan*, 2017 WL 4803941, at \*39 (emphasis added and internal citations omitted). Based on this, the Court accorded the PTO examiner's finding of unexpected results no weight because it was based on inaccurate evidence provided by Allergan. *Id.*

102. Had Allergan made clear to the PTO examiner that the Schiffman Declaration statements and data were lifted from prior art known to Allergan for over 10 years, as its Duty of Disclosure, Candor, and Good Faith required, the PTO examiner would have rejected all of the 2013 applications for the same reasons it had repeatedly denied every other prior application: that the claims presented were all obvious in light of the prior art.

**C. Allergan Wrongfully Lists Invalid Second Life Patents in the Orange Book**

103. The first of the Second Life Patents—the ‘111 patent—issued on January 14, 2014, which Allergan immediately listed in the Orange Book. This listing thus forced any ANDA filer seeking to market generic Restasis to file a certification as to the purportedly new patent.

104. The FDA has acknowledged, however, that shortly before the issuance of the ‘111 patent, the Agency had received at least one ANDA for generic Restasis. Up until the listing of the Second Life Patents, ANDAs may have been filed with paragraph ii and/or iii certifications, which meant that the generic would not be marketed until after expiration of Ding I in May 2014, just months away. Had Ding I simply expired in May 2014 without Allergan’s machinations, any paragraph ii and/or iii certified ANDAs would have been approved, generic Restasis would have been available as early as May 17, 2014, and generic competition to Restasis during the Class Period would have created immediate benefits to the Class in the form of lower prices.

105. Instead, all prior ANDA filers now had to amend their ANDAs to include certifications with respect to the ‘111 patent (and eventually the other Second Life Patents). Worse, the confusion Allergan created by its eleventh-hour patent applications and Orange Book listings meant that the order in which the FDA received any prior ANDA certifications likely was different than the order in which the agency received the paragraph iv certifications with respect to the Second Life Patents, creating various first-filer status uncertainties.

106. The wrongful Orange Book listings had another immediate impact: they effectively required all ANDA applicants to file paragraph iv certifications with respect to the Second Life Patents, which thereby enabled Allergan to sue for infringement and trigger the automatic stay of any FDA approval of such ANDA for up to 30 months. In contrast, paragraph ii or iii-certified ANDAs are not subject to that automatic 30-month stay of FDA approval.

107. Allergan knew when it listed the Second Life Patents in the Orange Book that such patents were invalid but nevertheless would provide Allergan a basis to delay generic competition to Restasis beyond May 2014 and otherwise would create confusion that would further chill the FDA's ANDA approval process.

**D. One or More ANDA Applicants Would Have Been Ready, Willing, and Able to Manufacture and Distribute Commercial Quantities of Generic Restasis in May 2014 Upon Expiration of Ding I**

108. Beginning in 2011, and continuing in 2012 and thereafter, numerous pharmaceutical manufacturers—including some of the biggest brand and generic pharmaceutical companies in the world—submitted ANDAs seeking the FDA's approval to market generic Restasis. Upon information and belief, but for Allergan's misconduct as alleged herein, one or several of these ANDA filers would have received FDA approval and would have been able to supply the market with generic Restasis as early as the expiration of Ding I in May 2014. Other ANDA applicants would have been ready at a later date but still within the relevant period.

109. The long list of generic companies that to date have filed ANDAs seeking to market generic Restasis includes Watson, Teva, Mylan, Akorn, Apotex, Innopharma (a Pfizer subsidiary), Famy Care, TWi Pharmaceuticals, and Deva Holding. But for the resource-drain, confusion, and administrative delays on the FDA and Restasis ANDA filers that resulted from Allergan's improper Orange Book listing, citizen petitions, and patent suits, some or all of these generic competitors would have been approved and on the market at an earlier period, beginning as early as May 2014—over 30 months after the first ANDA seeking approval for generic Restasis was filed with the FDA—and in any case well before now.

110. The existence of multiple Orange Book-listed patents, multiple citizen petitions concerning generic-approvability standards, ongoing patent litigation, and especially the accumulation of the foregoing, can act as a disincentive for companies who are considering

whether and when to aggressively pursue submission and approval of a particular ANDA. The process of contesting even baseless (but complicated) legal or scientific assertions necessarily adds to the time and resources required for the generic-approval process, both with respect to the ANDA applicants seeking generic approval and the FDA in reviewing those applications, all of whom must set priorities to allocate limited resources.

111. ANDA filers are less likely to aggressively pursue the filing or approval of ANDAs when faced with these added hurdles and complications, and the FDA has fewer resources available for legitimate scientific research when it is forced to respond to a series of extensive but baseless citizen petitions. Moreover, the FDA has policies to prioritize or expedite review of ANDAs that otherwise have a clear path to market (as would have been the case for Restasis ANDAs as of May 2014 were it not for Allergan's fraudulently obtained patents and wrongful petitioning).

112. The Restasis ANDA filers that waded into this Allergan-orchestrated morass had no choice but to contend with the resulting hurdles. As Mylan's CEO Heather M. Bresch stated in Mylan's November 3, 2017 earnings call, "I think this is a great example of [Mylan] persevering through what I would call [Allergan's] pretty desperate legal maneuvers to try to maintain a monopoly that should have been gone a couple of years ago, and our ability continue to fight not only in the courts, but with the science and have a clear pathway to approvals." And in an August 2016 investors' call, Akorn confirmed that it had "already partnered with someone to manufacture the [Restasis generic] product" and that the manufacturing partnership had "already been lined up, and filed."

113. Had scientists, regulatory professionals, and lawyers at Mylan, other generic manufacturers, and the FDA not been tied up by Allergan's "desperate legal maneuvers," and had

they not been forced for years to “continue to fight” Allergan’s anticompetitive conduct, they would have remained focused solely on ensuring that safe and effective generic versions of Restasis were approved “years ago” at, or as near as possible to, the expiration of the ’979 patent in May 2014. The delay in generic competition is a direct result of Allergan’s anticompetitive scheme and the exact result that Allergan intended to achieve.

**E. Allergan Files Sham Patent Infringement Suits to Delay Generic Entry**

114. In response to Allergan’s Orange Book listings, and exactly as Allergan had planned, generic competitors provided paragraph iv certifications with respect to the Second Life Patents. Generic manufacturers Akorn, Mylan, Teva, Apotex, and Pfizer subsidiary Innopharma all submitted paragraph iv certifications within weeks of each other starting in July 2015, asserting that the Second Life Patents either were invalid or not infringed. Because the patents were procured by fraud and otherwise invalid as obvious in light of Ding I and other prior art, Allergan had no legitimate basis to enforce them. Yet Allergan responded to each of the above paragraph iv certifications by filing patent infringement actions in the Eastern District of Texas, beginning on August 24, 2015.

115. These infringement suits triggered the automatic 30-month stay of any FDA final approval of these ANDAs filed after the Second Life Patents were listed.

116. On October 16, 2017, after trial in August, this Court found the Second Life Patents invalid based on obviousness. In the 135-page post-trial Findings of Fact and Conclusions of Law, this Court found that Allergan had secured these Patents “by way of a presentation that was more advocacy than science.” *Allergan*, 2017 WL 4803941, at \*64. This Court found particularly compelling the 2009 concessions, the fact that Allergan’s “unexpected” results were foreseeable based on the early cyclosporine studies, and that in any event, the “new” Restasis formulation

claimed by the Second Life Patents had statistically the same efficacy as one of the prior art examples in Ding I.

117. This Court also dismissed other arguments Allergan made at trial, including assertions that the allegedly surprising results arose from a difference between the Phase 2 and 3 studies, and that there were objective, valid reasons for issuing new patents:

While Allergan has pointed to evidence of objective considerations such as commercial success and long-felt unmet need, the force of that evidence is considerably blunted by the fact that, based on protection from a succession of patents, Allergan was able to foreclose competition in cyclosporin/glyceride emulsion formulations from the early 1990s until 2014. And the issuance of the [Second Life] Restasis patents has barred any direct competition for Restasis since then. The evidentiary value of the objective consideration evidence has thus been considerably weakened by the existence of blocking patents during the critical period.

*Id.* at \*65.

118. Allergan brought these multiple infringement suits regardless of any objective merit, and indeed, the suits were objectively baseless. Allergan conceded in 2009 that the claims in the '857 and '177 applications (the basis for what issued as Second Life Patents) were obvious in light of Ding I, and Allergan knew it had obtained the Second Life Patents only through its fraudulent misrepresentations to the PTO. Accordingly, there never was any objective merit to any of these infringement suits, and Allergan knew or should have known that the suits were objectively baseless. The objective merits were irrelevant, however, to Allergan's true purpose, which was not to vindicate any legitimate patent rights, but instead, to improperly use governmental process and the workings of the Hatch-Waxman act to delay generic competition to its Restasis monopoly.<sup>4</sup> If it filed even the most baseless of patent infringement suits, Allergan

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<sup>4</sup> Indeed, Allergan's subjective intent in filing these suits is evident from the complaint it filed. In its prayer for relief, Allergan demanded that this Court order, notwithstanding any lack of authority

knew it would still obtain and immediately benefit from the automatic 30-month stay of FDA final approval of any generic Restasis product. For a \$1.4 billion per year franchise, every extra month Allergan could postpone competition from generic Restasis added another \$125 million to its revenues.

#### **F. Allergan Abuses Citizen Petition Process to Delay Generic Entry**

119. Allergan also delayed the FDA's approval of any Restasis ANDAs by abusing the agency's citizen petition process. Namely, Allergan repeated the same baseless request to the agency in some fourteen redundant filings submitted over the course of four years, all of which were intended to delay the agency's approval of generic Restasis.

120. On June 20, 2013, the FDA issued non-binding draft guidance that gave Restasis ANDA applicants two options to demonstrate bioequivalence to branded Restasis: (1) *in vivo* testing (i.e., testing performed on live humans) or (2) *in vitro* testing (i.e., testing performed outside of a living organism, such as in a test tube). Generic-drug makers typically use *in vitro* testing in their ANDAs because it's less expensive and less time-consuming than the *in vivo* clinical trials that brand-name drug companies generally undertake—studies that the FDA believes “may present economic and logistical challenges for ANDA sponsors.” Ltr. from J. Woodcock to D. Burrow Re: Docket No. FDA-2014-P-0304, at 13 (Nov. 20, 2014) (“FDA 2014 Denial”). And as the agency later explained, allowing for *in vitro* testing makes particular sense with respect to Restasis, which is a type of drug that renders *in vivo* tests generally unreliable. *See* FDA 2014 Denial at 11-13.

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to do so, that “the effective date of any FDA approval” of any Restasis ANDA be “a date which is not earlier than the latest expiration date . . . including any extensions or periods of exclusivity” of the Second Life Patents. *See* Amended Complaint, *Allergan, Inc. v. Teva Pharms. USA, Inc.*, No. 2:15-cv-01455-WCB, ECF 96 (E.D. Tex. Feb. 18, 2016), at 127, 129, 131, 132.

121. The FDA solicited public comments on this draft guidance, which the agency noted it would consider before finalizing any Restasis bioequivalence requirements. In response, Allergan submitted a lengthy comment to the FDA on August 17, 2013. *See Allergan, Inc., Comment re Docket No. FDA-2007-D-0369—June 2013 Draft Bioequivalence Guidance for Cyclosporine Ophthalmic Emulsion, 0.05%* (Aug. 17, 2013). In it, Allergan insisted that the FDA could not approve any Restasis ANDAs relying on *in vitro* testing and asked the FDA to revise its guidance to reflect this. *See, e.g., id.* at 1. Allergan’s argument—which the FDA would reject, repeatedly—was essentially that topical medications like Restasis (e.g., medications applied to the skin) have historically presented a number of problems that make *in vitro* comparisons inherently unreliable. *See, e.g., id.* at 17-22. Allergan’s criticism of the draft guidance was supported by comments submitted by several doctors who—unbeknownst to the FDA—had received payments of up to \$70,000 from Allergan for “consulting” on Restasis.<sup>5</sup>

122. But Allergan knew that its draft-guidance comments would not necessarily delay generic entry because the FDA is only required to consider these comments; it isn’t required to formally respond to them. The agency generally must respond to citizen petitions, which can take years to resolve, regardless of a petition’s baselessness. Accordingly, despite having already called for mandatory *in vivo* testing in its draft-guidance comments, Allergan reiterated this demand in a series of redundant citizen petitions that it began filing with the FDA in January 2014—a tactic

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<sup>5</sup> For example, Drs. Marc Bloomenstein, Jai Parekh, and Stephen Pflugfelder all filed comments on the draft guidance that were critical of an *in vitro* bioequivalence option, but neither they nor Allergan disclosed that Allergan had repeatedly paid them for their work on Restasis. *See ProPublica, Dollars for Docs—Dr. Marc Bloomenstein, available at <https://projects.propublica.org/docdollars/doctors/pid/25861>* (last visited Dec. 8, 2017); *ProPublica, Dollars for Docs—Dr. Jai Parekh, available at, <https://projects.propublica.org/docdollars/doctors/pid/37605>* (last visited Dec. 8, 2017); *ProPublica, Dollars for Docs—Dr. Stephen C Pflugfelder, available at <https://projects.propublica.org/docdollars/doctors/pid/356009>* (last visited Dec. 8, 2017).

that Allergan even described to its investors as exemplifying its response to “intense competition from generic drug manufacturers.”<sup>6</sup>

123. Allergan submitted the first of these citizen petitions to the FDA on January 15, 2014, a day after Allergan improperly listed its first Second Life Patent in the Orange Book. This petition was followed by another citizen petition filed on February 28, 2014, which essentially parroted Allergan’s August 2013 comments. This February 2014 citizen petition requested—as Allergan had in August 2013—that the FDA “make clear that the only way to demonstrate bioequivalence to Restasis is through comparative clinical endpoint studies [i.e., *in vivo*]” and “not accept for filing . . . any ANDA referencing RESTASIS” that fails to do so. The February 2014 Citizen Petition cited to the public comments submitted by its cadre of paid doctors, ostensibly “draw[ing] from their clinical experience, criticizing the draft guidance’s *in vitro* approach.” Allergan further supplemented this petition on May 29, 2014, and again on October 31, 2014.

124. In the FDA 2014 Denial, issued on November 20, 2014, the FDA largely rejected Allergan’s petition, noting that the petition largely duplicated Allergan’s 2013 draft-guidance comments (FDA 2014 Denial, at 2 n.5), and explaining that existing statutes, regulations, and case law provide the agency with “considerable flexibility” in determining how best to establish bioequivalence (*id.* at 5). The agency then described the important policy goals underlying this flexibility:

The Agency’s authority to make bioequivalence determinations on a case-by-case basis using *in vivo*, *in vitro*, or both types of data enables FDA to effectuate several long-recognized policies that protect the public health: (1) refraining from unnecessary human research when other methods of demonstrating bioequivalence meet the statutory and regulatory standards for approval; (2) permitting the Agency to use the latest scientific advances in approving drug products; (3) protecting the public by ensuring only safe effective

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<sup>6</sup> Allergan, Inc., SEC Form 10-K for FY Ended 12-31-2014 at 12, 48.

generic drugs are approved for marketing; and (4) making more safe and effective generic drugs available.

*Id.* at 7–8 (citations omitted).

125. The FDA then explained that with respect to “locally acting, non-systemically absorbed drug products” like Restasis, the *in vivo* studies urged by Allergan’s citizen petition were “usually of limited utility.” *Id.* at 8. The FDA then noted that while its 2013 draft guidance for Restasis ANDAs had recommended using either *in vivo* or *in vitro* studies, the “modest efficacy demonstrated by Restasis” meant that an *in vivo* bioequivalence study “may not be feasible or reliable.” *Id.* at 11. The FDA then explicitly rejected Allergan’s request that Restasis ANDAs based on *in vitro* bioequivalence studies be rejected, telling Allergan that the FDA concluded that “an *in vitro* study is likely more sensitive, accurate, and reproducible than a comparative clinical endpoint study to establish bioequivalence” for generic Restasis. *Id.* at 13.

126. Because of this, the FDA reiterated its recommendation that Restasis ANDA holders have the option of relying on certain *in vitro* studies to prove bioequivalence. In essence, the agency suggested that generic companies could prove—via *in vitro* studies—that their generic Restasis was sufficiently physically identical to the brand product, which would in turn support bioequivalence (*id.* at 11–16): a method that the FDA had already substantiated with scientific studies and recommended with regard to several other drugs (*id.* at 12 n.42, 17–19). The agency then demonstrated that Allergan’s attacks on these *in vitro* studies were baseless and thus rejected Allergan’s citizen petition in its near entirety.

127. Nevertheless, barely a month after the FDA denied its first citizen petition, Allergan filed another on December 23, 2014. This petition essentially repeated the prior petition’s arguments and demanded—again—that the FDA require Restasis ANDA filers to conduct *in vivo*

testing.<sup>7</sup> Allergan would go on to supplement this petition four times throughout 2015, each time making new demands on the FDA that—while baseless—would nevertheless require a thorough agency response. Allergan’s August 26, 2015 supplement, for example, demanded to know which *in vitro* methods the FDA intended to accept before the agency actually finalized its guidance, and even requested that the FDA convene a committee of outside experts to evaluate the use of *in vitro* methods.<sup>8</sup> In September of 2015, Allergan also took the opportunity to repeat its *in vivo* arguments in a response to the FDA’s “Dear ANDA Applicant” letter<sup>9</sup>—a letter soliciting the views of Restasis ANDA holders on certain administrative issues, and not soliciting the views of Allergan on the scientific approval process.

128. On February 10, 2016, the FDA once again substantively denied Allergan’s citizen petition. The FDA noted that the December 2014 citizen petition “repeats many of the assertions that were at the center of Allergan’s previous petition” and declined to repeat the FDA’s earlier answers.<sup>10</sup> The FDA also expressed continued doubts about *in vivo* studies and even revised its guidance to recommend that ANDA applicants contemplating one first submit the study protocol to the FDA for review. FDA 2015 Denial at 15. Elsewhere, the FDA noted that some of Allergan’s

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<sup>7</sup> Allergan justified the filing in part by noting that, in its response to Allergan’s first petition, the FDA had mentioned that it was “considering revising” its draft guidance. Allergan Dec. 23, 2014 Citizen Petition at 2. But the revisions that the FDA was considering concerned ways of strengthening its proposed *in vitro* test, such as specifying what equipment could be used to perform it. *See* FDA 2014 Denial at 19; *see also id.* at 17 n.55 (considering revising to specify certain *in vitro* methodologies); *id.* at 25 (considering revising to specify a new factor that should be tested for *in vitro*). Not once did the FDA suggest that it was considering abandoning the *in vitro* option.

<sup>8</sup> Allergan Aug. 26, 2015 Fourth Supplement.

<sup>9</sup> Ltr. from D. Moxie to Division of Dockets Management (HFA-305), FDA, Re: Docket No. FDA-2015-N-2713—Abbreviated New Drug Applications for Cyclosporine Ophthalmic Emulsion, (Sept. 28, 2015).

<sup>10</sup> *See* Ltr. from J. Woodcock to D. Moxie & R. Bellantone re Docket Nos. FDA 2015-P-0065 and FDA-2015-P-1404 (Feb. 10, 2016) (“FDA 2015 Denial”), at 13.

claims—many of them repeated from the prior Petition—“[n]ot only . . . lack legal support, they also rest on flawed logic.” *Id.* at 37.

129. Perhaps most fundamentally, the FDA also faulted Allergan’s “various claims and assertions” for being “premature.” *Id.* at 13. The FDA reminded Allergan that its citizen petitions were attacking *draft* guidance, which was a “living, science-based document” that was already subject to public comment. *Id.* at 14. And because Allergan had already commented on this guidance, and because the FDA was already planning on reviewing these comments and considering them before finalizing the guidance (*id.* at 15), Allergan’s citizen petitions were unnecessary, if not inappropriate. Put differently, there was no reasonable basis to assume that these petitions would accomplish anything that could not already be accomplished via public commentary.

130. Perhaps recognizing this, Allergan submitted additional comments on the draft guidance on December 5, 2016.<sup>11</sup> However, the following August, Allergan submitted a third citizen petition. This petition predictably requested—again—that the FDA refuse to accept or approve any pending ANDAs unless supported by *in vivo* clinical endpoint studies. Allergan supplemented this petition on October 13, 2017.

131. While the FDA has substantively denied Allergan’s lengthy petitions, the FDA was still obligated to fully respond to each of them, and those responses diverted time and resources away from the ANDA approval process. In fact, in its February 2016 denial of Allergan’s December 2014 citizen petition, the FDA not only noted that Allergan’s petitioning was delaying the approval of any Restasis ANDAs, it suggested that this delay was caused by the need to respond

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<sup>11</sup> Ltr. from D. Moxie to Division of Dockets Management, FDA re Docket No. FDA-2007-D-0369—Comments on October 2016 Draft Guidance on Cyclosporine (Dec. 5, 2016).

to baseless arguments.<sup>12</sup> Allergan's serial sham petitioning has thus successfully delayed FDA approval of any Restasis ANDAs, as Allergan intended.

### **G. Allergan Enters Sham Agreement with the Tribe**

132. Allergan's latest effort to forestall competition in the market for cyclosporine stems from a series of IPR requests. In June 2015, Apotex, which subsequently provided Allergan notice of its Second Life Patent paragraph iv certifications on July 23, 2015, was the first ANDA applicant to petition the PTAB to initiate an IPR review of the Second Life Patents. *See, e.g., Pet. for Inter Partes Review*, IPR2015-01283 (Jun. 4, 2015). Allergan settled the Apotex IPR proceedings in December 2015, on undisclosed terms, just days before the PTAB was set to determine the likelihood that the PTAB would invalidate the Second Life Patents. *See, e.g., Judgment, Termination of Proceeding*, IPR2015-01283 (Dec. 16, 2015). By that time, however, other ANDA applicants, including Mylan and Teva, had also petitioned the PTAB for IPR proceedings on the Second Life Patents. In December 2016, the PTAB resolved the very same question that the Allergan settlement with Apotex mooted the year before, concluding that there was a reasonable likelihood that each of the Second Life Patents would be invalidated upon the PTAB's further review and thereby instituted proceedings against all six of the Second Life Patents.<sup>13</sup> *See, e.g., Decision, Institution of Inter Partes Review*, IPR2016-01128 (Dec. 8, 2016) ("[W]e determine that

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<sup>12</sup> More specifically, Allergan submitted data regarding a series of emulsions that it claimed passed the agency's *in vitro* test but were nevertheless *not* bioequivalent to Restasis. FDA 2016 Denial at 24. The FDA pointed out that none of these emulsions in fact met the *in vitro* test (*id.* at 24-26)—a fact that Allergan itself partially admitted (*id.* at 25-26 & n.107)—but the agency nevertheless obligated itself to fully respond to the emulsion data before approving any Restasis ANDAs (*id.* at 44).

<sup>13</sup> Because the terms of Allergan's settlement with Apotex in December 2015 (that avoided for as much as a year any risk that any of the Second Life Patents would be invalidated) were not made public, Plaintiffs are presently unable to determine the extent to which that settlement may have violated *Actavis*, 133 S. Ct. 2223, and thus constitute yet another component in Allergan's overall scheme.

Petitioner [Mylan] has shown that there is a reasonable likelihood that it would prevail with respect to at least one of the challenged claims.”).

133. On September 8, 2017—following the trial in front of this Court—Allergan entered into an ostensible agreement with the Saint Regis Mohawk Tribe (the “Tribe”) to convey ownership of the Second Life Patents to the Tribe with an exclusive license back to Allergan for “all FDA-approved uses in the United States” and a promise not to waive its sovereign immunity with respect to any IPR or other administrative action in the PTO related to the Patents. The Tribe did this in exchange for \$13.75 million from Allergan, plus potentially \$15 million in annual royalties. *Allergan*, 2017 WL 4619790, at \*1. On September 22, after the Tribe and Allergan agreed to this sham transfer of property rights, Allergan, using the Tribe as a conduit, petitioned the PTAB to dismiss the remaining pending IPRs for lack of jurisdiction based on tribal sovereign immunity.

134. No objectively reasonable litigant could expect these shenanigans before PTAB to succeed. Multiple cases have rejected similar schemes to game the law, including in the context of sovereign tribes where the only interest the tribe had was in being paid for the cover of immunity. *See People ex rel. Owen v. Miami Nation Enters.*, 386 P.3d 357 (Cal. 2016). This Court agreed to join the Tribe as a co-plaintiff, but only as a hedge to ensure that any judgment it rendered would apply to the Tribe as well. This Court explained that despite its “serious concerns about the legitimacy of the tactic that Allergan and the Tribe have employed,” it would “adopt the safer course of joining the Tribe as a co-plaintiff, while leaving the question of the validity of the assignment to be decided in the IPR proceedings, where it is directly presented.” *Allergan*, 2017 WL 4619790, at \*4.

135. Allergan has made no secret of its subjective bad faith in seeking to add the Tribe as a defendant in the IPRs. Allergan’s chief executive, Brent Saunders, explicitly acknowledged that Allergan pursued the deal with the Tribe not to advance competition on the merits, but rather to avoid what it inaptly called “double jeopardy,” that is, to intentionally disrupt adjudicative proceedings in one of the two venues, even though Allergan itself had initiated proceedings in the other and could voluntarily dismiss that other action at any time. Indeed, as the Court summarized, “The essence of the matter is this: Allergan purports to have sold the patents to the Tribe, but in reality it has paid the Tribe to allow Allergan to purchase—or perhaps more precisely, to rent—the Tribe’s sovereign immunity in order to defeat the pending [IPR] proceedings in the PTO.” *Id.* at \*2.

136. The Tribe, for its part, entered the agreement for the money. The Tribe is not entering the pharmaceutical industry, and, in fact, has publicly disclaimed any actual business interest in the pharmaceutical industry.<sup>14</sup> Licensing the Second Life Patents back to Allergan was not a natural outgrowth of any ownership interest the Tribe had prior to September 2017, and, from the Tribe’s comments, is not made pursuant to a natural future interest either. Nor was the Tribe acting in its sovereign capacity (e.g., regulating the sale or use of cyclosporine on a reservation) in entering its agreement with Allergan.

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<sup>14</sup> See Saint Regis Mohawk Tribe—Office of Technology and Research, Frequently Asked Questions about New Research and Technology (Patent) Business, at 1 (“[T]he Tribe is not investing any money in this business. Its only role is to hold the patents, get assignments, and make sure that the patent status with the US Patent Office is kept up to date.”), available at [https://www.srmt-nsn.gov/uploads/site\\_files/Office-of-Technology-Research-and-Patents-FAQ.pdf](https://www.srmt-nsn.gov/uploads/site_files/Office-of-Technology-Research-and-Patents-FAQ.pdf) (last visited Dec. 8, 2017).

## VII. MARKET POWER AND DEFINITION

137. The relevant geographic market is the United States and its territories and possessions.

138. At all relevant times, Allergan's share of the relevant cyclosporine ophthalmic emulsion market was and remains 100%.

139. At all relevant times, Allergan had monopoly power in the market for Restasis and its AB-rated generic equivalents because it had the power to maintain the price of Restasis at supracompetitive levels without losing substantial sales to other products prescribed and/or used for the same purposes as Restasis, with the exception of AB-rated generic cyclosporine ophthalmic emulsion products. This market power may be shown directly, and therefore no relevant market needs to be defined.

140. Allergan has enjoyed monopoly power conferred by the Ding I patent since 1995, and since 2003, when it launched Restasis pursuant to FDA approval, Allergan has reaped significant commercial benefits. When it received FDA approval in December 2002, Allergan touted Restasis as "the first and only therapy for patients with keratoconjunctivitis sicca (chronic dry eye disease-CDED) whose tear production is presumed to be suppressed due to ocular inflammation." In its numerous filings with the FDA, Allergan has similarly touted Restasis's uniqueness: "RESTASIS is a pathbreaking product that was developed to treat the widespread and sometimes debilitating problem of dry eye disease. Before RESTASIS, dry eye disease was a largely unmet medical need. After years of FDA-required clinical trials, Allergan was able to produce a precisely formulated drug that has significant efficacy in treating dry eye disease." Allergan Feb. 28, 2014 Citizen Petition at 13.

141. Manufacturers attempt to differentiate brand name drugs like Restasis based on features and benefits (including safety and efficacy), and not based on price. Doctors and patients

are generally price-insensitive when prescribing and taking prescription drugs like Restasis. This is due in part to the presence of insurance that bears much of the cost of prescriptions and other institutional features of the pharmaceutical marketplace. Different patients may respond differently to different drugs and even drugs within its same therapeutic class do not constrain the price of Restasis.

142. Other products are not practical substitutes for cyclosporine. Artificial tears offer only ephemeral relief and do nothing to address the underlying causes of dry eye. Corticosteroids can address the inflammation associated with dry eye, but have unwanted side effects, as do devices like “punctal plugs,” which block the tear ducts and help the eye retain naturally produced tears for longer. Patients treated with cyclosporine would not switch to these products in response to a small but significant non-transitory increase in the price of cyclosporine in sufficient numbers to make such a price increase by a hypothetical monopolist unprofitable. Shire US, Inc.’s introduction last year of its rival DED product, Xiidra, has not resulted in lower Restasis prices, thus confirming Allergan’s continued market power over the relevant cyclosporine market.<sup>15</sup>

143. Allergan’s ability to double the price of Restasis over the past decade without loss of significant sales further demonstrates lack of substitutability between Restasis and other drug products.<sup>16</sup> Restasis does not exhibit significant, positive cross-elasticity of demand with respect to price with any other DED medication. Other various DED treatments may exist, but none exhibit

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<sup>15</sup> It may be that Allergan is also improperly using its monopoly power in the cyclosporine market to unlawfully restrain Xiidra sales. In a recently filed antitrust complaint, Shire alleges that Allergan has engaged in an “ongoing, overarching, and interconnected scheme to systematically block Shire from competing with Allergan.” Complaint, *Shire US, Inc. v. Allergan, Inc.*, No. 2:17-cv-07716, ECF 1 (D.N.J. Oct. 2, 2017), at ¶ 1.

<sup>16</sup> See David Crow, *Allergan deal with Mohawk tribe casts patent shadow*, FINANCIAL TIMES (Sept. 27, 2017) (“The average wholesale price of a 30-dose pack of Restasis has more than doubled from \$117 in 2008 to almost \$280 today.”), available at <https://www.ft.com/content/5ec7305a-9f17-11e7-9a86-4d5a475ba4c5> (last visited Dec. 8, 2017).

cross-price elasticity with and therefore do not constrain the price of Restasis. The existence of these non-cyclosporine products that may be used to treat similar indications as Restasis did not constrain Allergan's ability to raise or maintain Restasis prices without losing substantial sales. Indeed, Allergan raised its prices almost 10% just months after Shire's launch of Xiidra. Therefore, those other drug products are not in the same relevant antitrust market as Restasis. Therapeutic alternatives, to the extent existent, are not the same as economic alternatives.

144. Functional similarities between Restasis and other DED medications, other than AB-rated generic Restasis equivalents are insufficient to permit inclusion of those other molecules in the relevant market with Restasis. To be an economic substitute for antitrust purposes, a functionally similar product must also exert sufficient pressure on the prices and sales of another product, so that the price of that product cannot be maintained above levels that would otherwise be maintained in a competitive market. No other DED medication (except for AB-rated generic versions of Restasis) will take away sufficient sales of Restasis to prevent Allergan from raising or maintaining the price of Restasis above levels that would otherwise prevail in a competitive market.

145. Restasis is also not reasonably interchangeable with any products other than AB-rated generic versions of Restasis because Restasis has significantly differentiating attributes making it a unique drug product. The FDA does not consider Restasis interchangeable with any other pain medication. Nor does Allergan. For example, Restasis is a topical ophthalmic formulation, and as Allergan has explained, "[u]nlike other drug delivery routes, a topical ophthalmic formulation usually delivers drug to the ocular tissues in relatively short timeframe of a few minutes." Allergan, Inc., Comment re Docket No. FDA-2007-D-0369—June 2013 Draft Bioequivalence Guidance for Cyclosporine Ophthalmic Emulsion, 0.05%, Aug. 17, 2013, at 13.

146. Allergan needed to control only Restasis and its AB-rated generic equivalents, and no other products, to maintain the price of Restasis profitably at supracompetitive prices while preserving all or virtually all of its sales. Only the market entry of a competing, AB-rated generic version of Restasis would render Allergan unable to profitably maintain its current prices of Restasis without losing substantial sales.

147. Allergan also sold Restasis at prices well in excess of marginal costs, and substantially in excess of the competitive price, and enjoyed high profit margins.

148. Allergan has exercised its power to exclude and restrict competition to Restasis and its AB-rated equivalents.

149. Allergan, at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market of cyclosporine ophthalmic emulsion due, in large part, to legally and illegally created patent protections, legally and illegally created regulatory bars to FDA approval of AB-rated generic competitors, and high costs of entry and expansion.

150. To the extent Plaintiff is legally required to prove monopoly power through circumstantial evidence by first defining a relevant product market, Plaintiff alleges that the relevant market is all cyclosporine ophthalmic emulsion products (i.e., Restasis in all its dosage strengths, and its AB-rated generic equivalents). During the period relevant to this case, Allergan has been able to profitably maintain the price of cyclosporine ophthalmic emulsion products well above competitive levels.

## **VIII. MARKET EFFECTS AND CLASS DAMAGES**

151. But for the anticompetitive conduct alleged above, multiple generic manufacturers would have entered the market with their generic cyclosporine ophthalmic emulsion products starting as early as May 17, 2014, when the exclusivities associated with Ding I and related patents expired. Instead, Allergan willfully and unlawfully maintained its monopoly power in the market for cyclosporine ophthalmic emulsion through a scheme to exclude competition. The scheme forestalled generic competition and carried out its anticompetitive effect of maintaining supracompetitive prices for Restasis.

152. Allergan implemented its scheme by fraudulently obtaining the Second Life Patents, wrongfully listing these knowingly invalid patents in the Orange Book, prosecuting sham patent infringement lawsuits against the generic manufacturers, submitting sham citizen petitions to the FDA and otherwise abusing the Hatch-Waxman framework, and entering into an anticompetitive agreement with the Tribe in a blatant attempt to insulate the Second Life Patents from invalidation in the PTAB IPR proceedings. These acts, individually and in combination, were anticompetitive.

153. If Allergan had not defrauded the PTO, the Second Life Patents would never have issued, and Allergan could never have used those Second Life Patents to block or forestall generic competition by asserting them in sham lawsuits and/or by wrongfully listing them in the Orange Book. Likewise, if Allergan had acted in good faith, it would not have abused the court process by filing lawsuits predicated on the knowingly invalid Second Life Patents against would-be makers of generic cyclosporine ophthalmic emulsion products, the filing of which automatically stayed any FDA final approvals of all generic alternatives. Had Allergan refrained from fraudulently obtaining the Second Life Patents and/or filing the sham lawsuits, AB-rated generic Restasis

manufacturers would have been able to launch generic cyclosporine ophthalmic emulsion products as early as May 17, 2014.

154. Allergan's anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Restasis from generic competition. Allergan's actions allowed it to maintain a monopoly and exclude competition in the market for cyclosporine ophthalmic emulsion, i.e., Restasis and its AB-rated generic equivalents.

155. Allergan's exclusionary conduct has delayed generic competition and unlawfully enabled it to sell Restasis without generic competition. But for the illegal conduct of Allergan, one or more ANDA-filers would have begun marketing generic versions of Restasis at least as early as May 17, 2014.

156. The generic manufacturers seeking to sell generic Restasis have extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs, marketing generic pharmaceutical products, and manufacturing commercial launch quantities adequate to meet market demand, and at least several of these generic manufacturers would have been ready, willing, and able to launch its generic version of Restasis as early as May 17, 2014, were it not for Allergan's unlawful acts.

157. Allergan's anticompetitive conduct, which delayed the introduction into the U.S. marketplace of any generic version of Restasis, has caused and will cause Plaintiff and the Class to pay more than they would have paid for cyclosporine ophthalmic emulsion, absent Allergan's unlawful conduct.

158. Typically, generic versions of brand-name drugs are initially priced significantly below the corresponding reference listed drug ("RLD") branded counterpart as to which they are AB-rated. As a result, upon generic entry, direct purchasers' purchases of brand drugs are rapidly

substituted for generic versions of the drug for some or all of their purchases. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further because of competition among the generic manufacturers, and, correspondingly, the brand name drug continues to lose even more market share to the generic versions of the drug.

159. This price competition enables all purchasers of the drug to: (a) purchase generic versions of a drug at substantially lower prices; (b) purchase generic equivalents of the drug at a lower price, sooner; and/or (c) purchase the brand drug at a reduced price. Consequently, brand manufacturers have a keen financial interest in delaying and impairing generic competition, and purchasers experience substantial cost inflation from that delay and impairment.

160. If generic competitors had not been unlawfully prevented from entering the market earlier and competing with Allergan, direct purchasers, such as Plaintiff and members of the Class, would have paid less for cyclosporine ophthalmic emulsion by (a) substituting purchases of less expensive AB-rated generic Restasis for their purchases of more-expensive branded Restasis, (b) receiving discounts on their remaining branded Restasis purchases, and/or (c) purchasing Restasis at lower prices sooner.

161. Thus, the unlawful conduct of Defendant deprived Plaintiff and the Class of the benefits of competition that the antitrust laws were designed to ensure.

## **IX. ANTITRUST IMPACT AND INTERSTATE COMMERCE**

162. During the relevant period, Plaintiff and members of the Class purchased substantial amounts of Restasis directly from Allergan. As a result of Allergan's unlawful anticompetitive conduct, members of the Class were compelled to pay, and did pay, artificially inflated prices for their cyclosporine ophthalmic emulsion requirements. Those prices were substantially greater than the prices that members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of brand-name Restasis was artificially inflated by

Defendant's illegal conduct, and (2) Class Members were deprived of the opportunity to purchase lower-priced generic versions of Restasis sooner.

163. As a consequence, Plaintiff and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

164. Allergan's efforts to monopolize and restrain competition in the market for Restasis have substantially affected interstate and foreign commerce.

165. At all material times, Allergan manufactured, promoted, distributed, and sold substantial amounts of Restasis in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

166. At all material times, Allergan transmitted funds as well as contracts, invoices and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Restasis.

167. In furtherance of its efforts to monopolize and restrain competition in the market for Restasis, Allergan employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. Allergan's activities were within the flow of and have substantially affected interstate commerce.

## **X. CLAIMS FOR RELIEF**

### **COUNT ONE**

#### **Violation of Section Two of the Sherman Act, 15 U.S.C. § 2: Monopolization Through *Walker Process* Fraud**

168. Plaintiff repeats and incorporates by reference all preceding paragraphs and allegations.

169. As described above, from 1995 until the present (and with continuing effects hereafter), Allergan possessed and continues to unlawfully possess monopoly power in the market

for Restasis (cyclosporine ophthalmic emulsion). During the relevant time period, no other manufacturer sold a competing version of any cyclosporine ophthalmic emulsion product in the United States.

170. Allergan willfully and unlawfully maintained its monopoly power in the Restasis market from May 17, 2014 through at least the present day by wrongfully asserting patents obtained by fraud to keep generic equivalents from the market—not as a result of providing a superior product, business acumen, or historical accident.

171. Allergan knowingly and intentionally asserted the invalid Second Life Patents in order to maintain its monopoly power. This was intended to block and delay, and had the effect of blocking and delaying, entry of AB-rated generic versions of Restasis.

172. Allergan, by and through its patent attorneys and scientists who submitted declarations in support of patentability (including Laura L. Wine, Dr. Rhett M. Schiffman, and Dr. Mayssa Attar), made misrepresentations of fact to the Patent and Trademark Office. These included:

- Statements by Allergan’s patent counsel that Dr. Schiffman’s declaration showed “surprisingly, the claimed formulation demonstrated a 8-fold increase in relative efficacy for the Schirmer Tear Test score in the first study of Allergan’s Phase 3 trials compares to the relative efficacy for the . . . formulation discussed in Example 1E of Ding, tested in Phase 2 trials. . . . This was clearly a very surprising and unexpected result.” *Allergan*, 2017 WL 4803941, at \*11.
- Statements by Allergan’s patent counsel that Dr. Schiffman’s declaration showed “the claimed formulations also demonstrated a 4-fold improvement in the relative efficacy for the Schirmer Tear Test score for the second study of Phase 3 and a 4 fold increase in relative efficacy for decrease in corneal staining score in both of the Phase 3 studies compared to the . . . formulation tested in Phase 2 and disclosed in Ding. This was clearly a very surprising and unexpected result.” *Id.*
- Figures 1-4 in Dr. Schiffman’s declaration reported figures from the Sall paper but omitted all error bars and p-values. In truth, as this Court later found, none of the pair-wise comparisons between the two cyclosporine formulations for corneal staining and Schirmer scores in the Phase 2 study or the pooled Phase 3 studies

demonstrated statistical significance at any time point, and many of the p-values for the pair-wise comparisons were very high. *Id.* at \*37. The actual statistical analyses showed that any observed difference in raw numbers between the cyclosporine formulations was likely the result of random chance. *Id.*

- Dr. Schiffman did not disclose to the PTO that he was comparing different Schirmer Tear Test scores—one without anesthesia in Phase 2 and one with anesthesia in Phase 3—in order to purportedly show a difference in efficacy. *Id.* As the Court later found, only the Schirmer Tear Test results with anesthesia in Phase 3 significantly favored the 0.05% cyclosporine formulation. “It was therefore only by comparing the results of two different types of tests that Dr. Schiffman was able to produce a significantly distorted picture suggesting that the [Phase 3 formulation] was much more effective than the [Phase 2 formulation]. This was both statistically and clinically improper. *Id.*
- Dr. Schiffman did not disclose to the PTO that the method he chose to calculate the differences in efficacy “exaggerated the difference in the raw values between the two.” *Id.* at \*38.
- The calculations in Dr. Schiffman’s table are misleading:
  - Dr. Schiffman used ratios of the degree of improvement, which tends to overstate the difference between the results.
  - Dr. Schiffman ignored the fact that the Phase 2 study was quite small, and that the difference in the raw numbers between formulations were not statistically significant.
  - Dr. Schiffman only included data from favorable comparisons between the two formulations. He omitted categories where the Ding I formulation did better than the Second Life Patents’ formulation.
- Dr. Schiffman did not tell the PTO that the data provided was taken from the Sall paper published more than a dozen years earlier (and three years before the priority date for the Restasis patents). Even if the results presented were surprising (they were not), they were publicly known before the date of invention and cannot be the basis for a claim that it was “unexpected” as of the Restasis patent’s priority date.

173. These representations were material. The examiner had repeatedly rejected the applications as obvious before Allergan’s misleading statements and omissions. The examiner had also earlier rebuffed Allergan’s purported secondary considerations of non-obviousness (including commercial success and unmet need). The PTAB’s later decision, as well as this Court’s later

decision, support the materiality of these misrepresentations and omissions. Indeed, according to this Court, Dr. Schiffman “agreed that it would be fair to say that his declaration was instrumental in persuading the Patent Office to grant the applications.” *Allergan*, 2017 WL 4803941, at \*20.

174. Allergan made these statements with intent to deceive the PTO. The misleading statements were made intentionally, not accidentally. Allergan was motivated to obtain a longer period of patent protection given the large sales of Restasis and the importance of the product to the company. The misleading statements were only made after the examiner rejected the application (not with the initial filing) and were made to overcome a rejection and support patentability. There is no innocent explanation for presenting the information as it was presented in the misleading declaration and accompanying submissions; the only reasonable inference is that Allergan intended to deceive the PTO.

175. The PTO reasonably relied on Allergan’s false and misleading statements in issuing the Second Life Patents. The examiner stated that the Schiffman declaration was deemed sufficient to overcome his earlier rejection based on Ding I because “Examiner is persuaded that, unexpectedly, the claimed formulation . . . demonstrated an 8-fold increase in relative efficacy for the Schirmer Tear Test score in the first study of Phase 3 trials compared to relative efficacy for the formulation disclosed in Ding I.” The Examiner also explained that the declarations “illustrate that the claimed formulations . . . also demonstrate a 4-fold improvement in the relative efficacy for the Schirmer Tear Test score for the second study of Phase 3 and a 4- fold increase in relative efficacy for decrease in corneal staining score in both of the Phase 3 studies compare to the . . . formulation tested in Phase 2 and disclosed in Ding.”

176. But for Allergan's misrepresentations and omissions, the Second Life Patents would not have issued. Had they not issued, there was no patent-based impediment to generic versions of Restasis entering the market from May 17, 2014, onwards.

177. Allergan listed the Second Life Patents in the Orange Book and later asserted them against all would-be generic competitors.

178. But for Allergan's asserting the fraudulently obtained patent, generic versions of Restasis would have been available as early as May 17, 2014, and in any case within the Class Period.

179. There is no valid procompetitive business justification for Allergan's anticompetitive conduct, and to the extent Allergan offers one, it is pretextual and not cognizable, and any procompetitive benefits of Allergan's conduct do not outweigh its anticompetitive harms.

## **COUNT TWO**

### **Violation of Section Two of the Sherman Act, 15 U.S.C. § 2: Monopolization Through an Overarching Anticompetitive Scheme**

180. Plaintiff repeats and incorporates by reference all preceding paragraphs and allegations.

181. As described above, from 1995 until the present (and with continuing effects hereafter), Allergan possessed and continues to unlawfully possess monopoly power in the market for Restasis (cyclosporine ophthalmic emulsion). During the relevant time period, no other manufacturer sold a competing version of any cyclosporine ophthalmic emulsion product in the United States.

182. Allergan has willfully and unlawfully maintained its monopoly power in the Restasis market from May 17, 2014, through at least the present day by engaging in an

anticompetitive scheme to keep generic equivalents from the market—not as a result of providing a superior product, business acumen, or historical accident.

183. Allergan knowingly and intentionally engaged in an anticompetitive scheme in order to maintain its monopoly power, the components of which either standing alone or in combination (in whole or part) were designed to block and delay, and in fact have blocked and delayed, entry of AB-rated generic versions of Restasis. This scheme included:

- Prosecuting serial baseless patent applications and ultimately obtaining the Second Life Patents by fraud through misleading the PTO and failing to exercise the Duty of Disclosure, Candor, and Good Faith;
- Improperly listing the Second Life Patents in the Orange Book;
- Engaging in multiple sham litigations;
- Submitting serial sham citizen petitions; and
- Abusing the PTAB's IPR process through the sham transfer of the Second Life Patents to the Saint Regis Mohawk Tribe.

184. By means of this scheme, Allergan intentionally and wrongfully maintained monopoly power with respect to Restasis in violation of Section 2 of the Sherman Act. As a result of this unlawful maintenance of monopoly power, Plaintiff and members of the Class paid artificially inflated prices for their cyclosporine ophthalmic emulsion requirements.

185. Plaintiff and members of the Class have been injured in their business or property by Allergan's antitrust violations. Their injury consists of having paid higher prices for their cyclosporine ophthalmic emulsion requirements than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type antitrust laws were designed to prevent, flows from that which makes Allergan's conduct unlawful, and Plaintiff and the Class are the proper entities to bring a case concerning this conduct.

186. Allergan knowingly and intentionally committed *Walker Process* fraud to induce the PTO to grant the Second Life Patents. Specifically, Allergan—after repeated denials of prior substantially similar serial applications over more than a 10-year period—submitted false sworn declarations in 2013 that Allergan characterized, by commission and omission, as presenting new data that showed surprising results not anticipated by prior art (i.e., Ding I), when in fact the data presented was neither new or surprising. Had Allergan made clear to the PTO examiner that the 2013 declarations statements and data were lifted from prior art known to Allergan for over 10 years, as Allergan’s Duty of Disclosure, Candor, and Good Faith required, the PTO examiner would have rejected all of the 2013 applications for the same reasons it had repeatedly denied every prior application: that the claims presented were all obvious in light of the prior art. Allergan’s misstatements were material, fraudulent, and made knowingly and with the intent to deceive, and in fact induced the PTO to issue the Second Life Patents.

187. Allergan knew when it listed the Second Life Patents in the Orange Book that these patents were fraudulently procured and/or were otherwise invalid as obvious in light of prior art, namely Ding I and the related patents, and that therefore the Second Life Patents should not have been listed in the Orange Book. Allergan knew that listing the Second Life Patents in the Orange Book would force ANDA applicants to file paragraph iv certifications that would thereby provide Allergan the opportunity to file patent infringement suits against those ANDA applicants that, regardless of the baselessness of such suit, could trigger an automatic stay of any FDA final approval of any new paragraph iv-certified ANDA applicant’s generic Restasis product for a period of up to 30 months.

188. Allergan knowingly and intentionally engaged in multiple sham litigations against manufacturers of AB-rated generic equivalents of Restasis. Allergan intentionally and deceptively

alleged the generic manufacturers' products infringed its Second Life Patents, knowing when those suits were filed that such patents were wrongfully obtained through fraud on the PTO and were otherwise invalid as obvious in light of the prior art, namely Ding I and the related patents. Allergan also knew, at the time those multiple sham suits were filed, that it had no realistic likelihood of success; that is, that there was no realistic likelihood that a court would enforce the fraudulently-obtained and otherwise invalid Second Life Patents against a generic company. Allergan knew, therefore, that no reasonable pharmaceutical manufacturer would have believed it had a reasonable chance of succeeding on the merits of these infringement lawsuits. Allergan filed this sham lawsuit for the purposes of using a governmental process as an anticompetitive weapon to keep generics off the market and wrongfully maintain its monopoly power over Restasis, regardless of any actual merit to its infringement claims.

189. Allergan knowingly and intentionally submitted multiple and serial sham citizen and other petitions to the FDA the purpose and intent to which was delay the FDA's approval of any of the pending generic ANDA applications, regardless of any objective merit to any part or parts of any petition.

190. Allergan knowingly and intentionally transferred the Second Life Patents to the Tribe—a sovereign tribe that does not manufacture or distribute pharmaceutical products of any kind and is better known for its operation of casinos on tribal lands located in New York—in an attempt to evade invalidation of those patents and cessation of its Restasis monopoly, which illustrates the extraordinary measures Allergan was willing to take in its stop-at-nothing desperation to delay competition.

191. Allergan's anticompetitive conduct as alleged herein is not entitled to any qualified *Noerr-Pennington* immunity, nor is it protected by the state-action doctrine.

192. There is no valid procompetitive business justification for Allergan's anticompetitive conduct, and to the extent Allergan offers one, it is pretextual and not cognizable, and any procompetitive benefits of Allergan's conduct do not outweigh its anticompetitive harms.

**COUNT THREE**  
**Violation of Section One of the Sherman Act, 15 U.S.C. § 1:**  
**Contract in Restraint of Trade**

193. Plaintiff repeats and incorporates by reference paragraphs all preceding paragraphs and allegations.

194. Defendant's contract with the Tribe is an unreasonable restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

195. Defendant's contract in restraint of trade and its other anticompetitive acts were intentionally directed at the United States Restasis market, and had a substantial and foreseeable effect on interstate commerce by interfering with potential generic competition for Restasis and raising and maintaining Restasis prices at supracompetitive levels throughout the United States.

196. As a result of the contract in restraint of trade, Allergan and the Tribe have effectively excluded competition from the Restasis market, allowing Allergan to unlawfully maintain its monopoly in the Restasis market, and both Allergan and the Tribe have profited from their illegal contract by maintaining prices at artificially high levels.

197. There is no legitimate business justification for the anticompetitive actions of Allergan and the Tribe and the conduct through which Allergan maintained its monopoly in the market, including the contract between Allergan and the Tribe. The anticompetitive effects of Allergan's and the Tribe's contract far outweigh any conceivable procompetitive benefit or justification.

198. As a direct and proximate result of Allergan's and the Tribe's unlawful actions, Plaintiffs and members of the Class have been and continue to be injured by their business or property.

199. As a direct and proximate result of Allergan's and the Tribe's unlawful actions, Plaintiff and the other members of the Class have been forced to pay artificially high, supracompetitive prices for Restasis and were harmed thereby.

200. Plaintiff and members of the Class are entitled to treble damages to remedy the injuries they have suffered from Allergan's and the Tribe's violations of Sherman Act Section 1, 15 U.S.C. § 1.

**COUNT FOUR**  
**Violation of Section Two of the Sherman Act, 15 U.S.C. § 2:**  
**Conspiracy to Monopolize**

201. Plaintiff repeats and incorporates by reference all preceding paragraphs and allegations.

202. Allergan and the Tribe have conspired to allow Allergan to willfully maintain and unlawfully exercise monopoly power in the Restasis market through the anticompetitive contract with the specific intent to monopolize the Restasis market, and preventing competition in the market.

203. As a result of the conspiracy, Allergan and the Tribe have effectively excluded competition from the Restasis market, unlawfully maintained Allergan's monopoly in the Restasis market, and profited from their anticompetitive conduct by maintaining prices at artificially high levels.

204. As a result of the contract in restraint of trade, Allergan and the Tribe have effectively excluded competition from the Restasis market, allowing Allergan to unlawfully

maintain its monopoly in the Restasis market. The anticompetitive effects of Allergan's and the Tribe's contract far outweigh any conceivable procompetitive benefit or justification. There is no legitimate business justification for the anticompetitive actions of Allergan and the Tribe and the conduct through which Allergan maintained its monopoly in the market. The anticompetitive effects of Allergan's and the Tribe's agreement far outweigh any conceivable procompetitive benefit or justification. As a direct and proximate result of Allergan's and the Tribe's unlawful actions, Plaintiffs and member of the Class have been and continue to be injured by their business or property.

205. As a direct and proximate result of Allergan's and the Tribe's unlawful actions, Plaintiff and the other members of the Class have been forced to pay artificially high, supracompetitive prices for Restasis and were harmed thereby.

206. Plaintiff and members of the Class are entitled to treble damages to remedy injuries suffered from Allergan's and the Tribe's violations of Sherman Act Section 2, 15 U.S.C. § 2.

## **XI. PRAYER FOR RELIEF**

WHEREFORE, Plaintiff, on behalf of itself and the Class, prays that the Court:

- i. Determine that this action may be maintained as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Federal Rule of Civil Procedure 23(c)(2), be given to the Class, and declare Plaintiff as a named representative of the Class;
- ii. Conduct expedited discovery proceedings leading to a prompt trial on the merits before a jury on all claims and defenses;
- iii. Enter judgment against Defendant and in favor of Plaintiff and the Class;
- iv. Award the Class damages (i.e., three times overcharges) in an amount to be determined at trial, plus interest in accordance with law;
- v. Award Plaintiff and the Class their costs of suit, including reasonable attorneys' fees as provided by law; and

- vi. Award such further and additional relief as is necessary to correct for the anticompetitive market effects caused by Defendant's unlawful conduct, as the Court may deem just and proper under the circumstances.

## **XII. JURY DEMAND**

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, on behalf of itself and the proposed Class, Plaintiff demands a trial by jury on all issues so triable.

Dated: December 11, 2017

Respectfully submitted,

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